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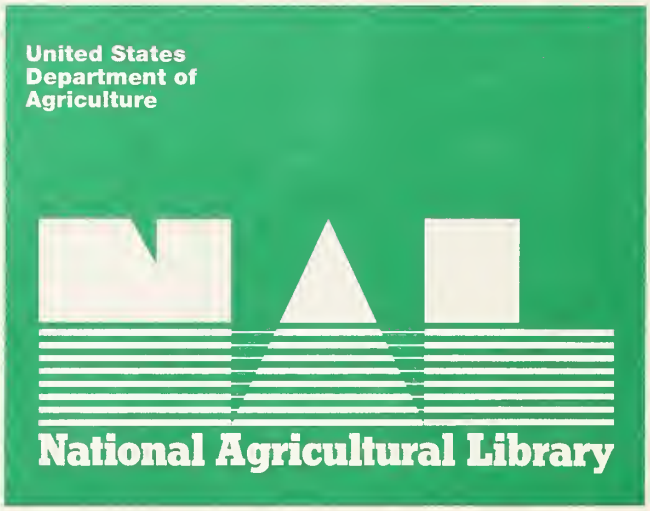
Food Safety
and Inspection
Service

April 1991

Hazard Analysis and Critical Control Points (HACCP) Evaluation Plan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Part One
Introduction and Evaluation Plan

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PART ONE—INTRODUCTION AND EVALUATION PLAN

The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture initiated in January 1990 a study to determine how to implement the Hazard Analysis and Critical Control Point (HACCP) system into meat and poultry inspection operations. The four-phase study includes consultations and public hearings to explain HACCP and the Agency's study, workshops to develop model HACCP plans, in-plant testing to test the model HACCP plans, and evaluation of the study and model HACCP plans.

The HACCP evaluation has five goals:

1. To evaluate the pre-implementation stages of HACCP models in the volunteer plants;

2. To evaluate the conformance of the model HACCP plans. and the plant-specific HACCP models with the HACCP principles developed by the National Advisory Committee on Microbiological Criteria for Foods;

3. To evaluate the functioning and effectiveness of the plant-specific HACCP models in the volunteer plants;

4. To evaluate the functioning and effectiveness of a HACCP-based inspection system in the volunteer plants; and

5. To evaluate the potential impact for nationwide implementation of a HACCP-based inspection system in meat and poultry plants.

The evaluation is intended to be an analytic study. Several methods and sources of data collection will be used to meet the study goals.

Evaluation Team

FSIS formed an interdisciplinary team—separate from the industry and other Agency groups involved in the development of HACCP models—to identify evaluation goals and tasks. The team included experts from FSIS microbiology, chemistry, mathematics and statistics, processing, slaughter and other staffs who reviewed the tasks and developed protocols for testing the model plans in the volunteer plants.

Evaluation Tasks

FSIS has identified 10 evaluation tasks to achieve the goals of the evaluation:

Peer-reviewed	Not Peer-reviewed
HACCP Model Checklist	Workshop Evaluation
National Profiles	Training
Quantitative Plant Data	Economic Impact
Qualitative Plant Data	Staffing
Literature Review	
Inspector and Plant Personnel Survey	

The Agency intends to evaluate the impact of a HACCP-based inspection program on training, staffing needs, and Agency and industry costs. The Agency also will assess the effectiveness of the workshop format in developing model HACCP plans. These tasks will not be peer-reviewed.

The HACCP model checklist will help determine whether the models conform with the HACCP principles developed by the National Advisory Committee on Microbiological Criteria for Foods.

The evaluation of the in-plant testing phase is based on the analysis of quantitative and qualitative data. The quantitative data will be obtained from sampling and testing of products, with emphasis on product-contact surfaces, the environment, and processes prior to implementation of the HACCP models and during the implementation of the models in volunteer plants. The results of the data collected during implementation of HACCP models will be compared with the baseline data.

The qualitative data will provide an overview of volunteer plant environments, management capabilities to control the manufacturing process, and management attitudes affecting quality assurance. FSIS will derive this data from interviews and questionnaires with in-plant inspectors and plant personnel, the observations of FSIS employees, and information from Agency experts and subject matter experts who are involved in the study. The qualitative data will be used as an adjunct to the quantitative data in reaching conclusions for the evaluation.

The national profile data will provide statistical information and will allow FSIS to make observations of similarities and differences between the conditions in the volunteer plants and the patterns shown in the national profile.

The Agency intends to keep confidential the evaluation data collected in the 15 test plants until the HACCP Study and the final report are completed. The final report will include an analysis of the plant data and Agency recommendations. The evaluation data would not be available under the Freedom of Information Act until the final report is published. However, the Agency cannot guarantee that the evaluation data will not be released. The Agency may be required to release the data if requested by Congress or ordered by a court. If the Agency is required to release the data prior to the conclusion of the study, then the Agency would provide predisclosure notification to the appropriate test plants.

Peer Review

FSIS selected six peers to review the draft HACCP Evaluation Plan. The peers submitted written comments and met March 7, 1991, with the FSIS Evaluation Team to discuss the evaluation plan. The peers provided 24 recommendations

(see Appendix E), all of which the Agency has accepted, and those recommendations are reflected in this final HACCP Evaluation Plan.

Workshops and In-Plant Testing

FSIS will hold five workshops for the following products: refrigerated foods (cooked and assembled products), cooked sausage, poultry slaughter, fresh ground beef and swine slaughter. During the workshops, industry technical experts will develop model HACCP plans for each product.

The model plans will then be implemented in volunteer plants. Three volunteer plants will be selected to test each HACCP plan. However, because of time constraints on the study, only three of the models (refrigerated foods, cooked sausage and poultry slaughter) and their in-plant implementation will be evaluated and peer-reviewed. The fresh ground beef and swine slaughter models will be tested in volunteer plants and evaluated by FSIS, but not peer-reviewed.

Limitations

FSIS recognizes the limitations of the evaluation. The characteristics of the available data and data sources—both qualitative and quantitative—must be identified and taken into account before analysis can be completed. Also, the explanatory value of the statistical analysis will be affected if changes are made in a plant's HACCP program during the study. Changes in the program will be documented by date, and data collected after changes are made will be separately grouped and calculated. In addition, because the HACCP models are being tested in only a few volunteer plants, any generalizations of the results of in-plant testing will have to be carefully qualified.

Summary

FSIS hopes the evaluation of its HACCP Study and model plans will yield both empirical results and fresh insights into the implementation of HACCP systems in a regulatory context. The evaluation should also enable the Agency to assess HACCP implementation from the perspective of the historic, international and interdisciplinary development of food safety and quality assurance concepts.

The evaluation is intended to be both critical and constructive, comprehensive and feasible, and the evaluation criteria have been chosen accordingly. As the Agency is committed to the principles of HACCP, so is it committed to the goals of the evaluation. Through its overall effort, it will learn how the principles of HACCP and quality systems can best be applied in meat and poultry production to improve process controls and public health protection.

A. The FSIS Inspection System

FSIS: The Agency and its Mission

The Food Safety and Inspection Service (FSIS) of the Department of Agriculture (USDA) is responsible for ensuring that meat, poultry, and meat and poultry products in interstate and foreign commerce are safe, wholesome, not adulterated, and accurately labeled. FSIS administers and enforces the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the regulations by which these laws are implemented.

Only federally inspected meat and poultry plants may sell their products in interstate or foreign commerce. In 1990, FSIS inspected 124 million head of livestock and 6.2 billion birds. FSIS inspected billions of pounds of processed products that entered the retail marketplace and more than 2.6 billion pounds of imported products.

More than 7,300 Federal inspectors, including some 1,200 veterinarians, enforce the inspection laws in about 6,900 meat and poultry plants. Livestock and poultry are inspected before slaughter to detect diseases or other abnormalities and their carcasses and organs are inspected again after slaughter. Meat and poultry products are inspected during processing, handling, and packing.

Control and condemnation of misbranded or adulterated products is one way FSIS ensures compliance with inspection laws and regulations. However, the Agency can take other actions if they are necessary to prevent adulterated or misbranded products from reaching consumers. These actions include temporarily halting inspection (and thus production) until serious problems are corrected, controlling product distribution, ensuring that companies recall violative products, and seeking court-ordered product seizures when necessary.

FSIS also monitors State inspection programs, which inspect meat and poultry products that will be sold only within the state in which they were produced. The 1967 Wholesome Meat Inspection Act and the 1968 Wholesome Poultry Products Inspection Act require State inspection programs to be "at least equal to" the Federal inspection program. If States choose to end their inspection programs or cannot maintain this standard, FSIS must assume responsibility for inspection.

The Agency also conducts unannounced reviews at refrigerated warehouses and other distribution points to monitor conditions and compliance, and spot-checks products in retail stores to verify continued safety and accurate labeling.

The Agency's many other programs, from laboratory services to food safety education, support the basic inspection function.

Slaughter Inspection

In general, animals amenable to the statutes and destined for human consumption are presented at an abattoir or poultry plant to be slaughtered, dressed and processed. Upon delivery to the plant, they are held in a designated area for ante-mortem inspection. From this area, they are driven or conveyed inside the plant where the animals are slaughtered, dressed, inspected and processed. Immediately upon entry into the plants, the animals are stunned to prevent pain before death. After slaughter, hide and hair or feathers are removed. The next step involves evisceration (removal of internal organs) and dressing (cleaning and preparation) of the exterior and interior carcass surfaces. Carcasses and edible parts are either passed, passed with restrictions, or condemned. In most plants, from the moment of stunning through the final dressing procedures, the carcasses are conveyed through the plant by a moving chain or belt. Poultry plants tend to be automated to a relatively high degree. In red meat plants, passed carcasses that are not being immediately "hot" deboned are moved to refrigerated rooms after final dressing, where they may be subject to chilling sprays. In poultry plants, inspected and passed carcasses are usually immersed in ice or cold water tanks to bring the carcass temperature down to acceptable levels to retard bacterial growth. After being chilled, the dressed carcasses may be prepared for sale as whole carcasses, or they may be cut up or subjected to some other form of processing before being shipped from the plant.

Federal inspection is conducted both before and after slaughter to ensure that carcasses and parts are free of disease or other conditions that may render them unfit for human food. Ante-mortem and post-mortem inspection are required to be performed on each animal, its carcass and parts.

Inspection of both red meat and poultry relies on organoleptic (visual, smell and touch) methods, which consist of observation of the carcass and viscera, and palpation and/or incision of certain internal organs to identify abnormalities or evidence of disease. However, the focus on sensory methods is changing. FSIS uses and is researching rapid tests and scientific diagnostics to identify conditions that make meat and poultry unfit for human consumption. FSIS inspection is also supported by microbiology, chemistry and pathology laboratory services. FSIS-operated and contract laboratories carry out analyses on samples obtained through directed and periodic sampling. The principal concerns are antibiotic and other chemical residues in raw meat and poultry, microbiological contamination of processed foods, incorrect meat or poultry species in the ingredients of processed foods, and correct formulation of the product.

Federal inspection is also directed at ensuring the environment in which slaughter and processing take place is a clean one. Facilities and equipment must be constructed to be capable of being maintained in a sanitary condition.

Poultry Slaughter Inspection

Because young chicken slaughter is a particular focus of the present study, it may be helpful to describe two of the more common inspection systems in use. The system most widely used in young chicken plants today is known as the Streamlined Inspection System (SIS). SIS includes an inspection procedure in which an inspector examines the viscera and the inside and outside surfaces of each carcass. After post-mortem inspection under SIS has been completed at the inspection station(s), plant employees perform any necessary outside trim on all passed carcasses after the giblets are harvested (gathered for packaging or further processing).

FSIS inspectors examine the outside, inside, and viscera of all birds presented for inspection. Inspection is conducted in two phases — a post-mortem inspection phase and a re-inspection phase. Plants with SIS are allowed to have two FSIS inspectors on each line (SIS-2) or one inspector on a line (SIS-1), depending on the line speed.

Every bird on the moving production line is presented to an inspector with its attached viscera hanging outside the bird. The birds must be presented in a uniform manner. The maximum inspection rate for SIS is 35 birds per minute for each inspector (a line speed of 70 birds per minute for SIS-2 and 35 birds per minute for SIS-1). Inspection rates may be adjusted by the inspector-in-charge on the basis of factors that interfere with carcass inspection (e.g., unacceptable or improper presentation of carcasses, excessive presence of disease in the flock, etc.) or factors that contribute to a sanitary risk along the evisceration line (e.g., excessive pile-up of birds at the salvage or reprocessing stations, or excessive carcasses on hang-back racks).

The Agency has developed guidelines for the presentation of carcasses in official poultry slaughter establishments. These guidelines provide objective criteria for determining acceptable presentation and for reducing the line speeds when presentation is less than acceptable — to ensure inspection can be performed adequately.

In the inspection phase of SIS, FSIS inspectors determine which birds must be salvaged, reprocessed, condemned, retained for disposition by a veterinarian, or allowed to be moved down the line as a "passed bird subject to re-inspection." If an inspector finds that some poultry carcasses have certain defects not requiring condemnation of the whole carcass, the inspector may pass the carcass, which is then subject to re-inspection to ensure the defects are physically removed. Trimming of birds that are passed is performed by plant employees.

The re-inspection station or stations are located at the end of the processing lines prior to chilling and after each chiller. At the pre-chill station, FSIS inspectors re-examine a random sample of carcasses by visually monitoring carcasses for defects or checking plant records. SIS incorporates a Finished Product Standards (FPS) program and a list of weighted defects to determine carcass acceptability. Products not complying with the finished product standards must be resampled and/or reworked to remove all defects. The inspectors score the presence of defects such as feathers, grease, and bruises on birds. The FPS program for SIS includes a pre-chill test that measures the effectiveness of processing controls and a post-chill test that reflects changes taking place during the chilling process.

The operation of the FPS program is the responsibility of the plant. Under SIS, the cumulative sum (CUSUM) statistical method is used to monitor finished product quality. In CUSUM, the data collected is used to determine the conformance of outgoing product with the standards. Prescribed action is taken on product that fails to meet the FPS, and both FSIS and plant personnel are alerted to developing or impending problems involving product non-conformance.

SIS-1 requires that the plant provide one inspection station for each line and re-inspection facilities adequate for the removal and examination of carcasses from each line. SIS-2 requires the establishment to provide two inspection stations for each line and similarly adequate re-inspection facilities. SIS requires adjustable inspection stands and stronger, better lighting.

Another system, the New Line Speed (NELS) inspection system, is a voluntary alternative system that allows plant operators to ensure control of their facilities, personnel, and processing procedures, in accordance with a written partial quality control (PQC) program approved by the Agency. The agreement provides the FSIS inspector-in-charge (IIC) with the documentation and other evidence that the plant is effectively controlling and monitoring all manufacturing processes critical to the processing of an acceptable product. However, inspection is still conducted on each bird and the inspection program verifies plant compliance.

Inspection of Processed Products

Inspected and passed carcasses may be subject to further processing. (A "processed" meat or poultry product is one that is subjected to some treatment that affects its texture, color, or flavor.) The processing may range from simple cut-up into parts or portions to more complex processing. Soups and stews, sausages, jerky, hams, frozen dinners, and meals

in retorted flexible pouches are among the many kinds of processed products.

While there are different manufacturing requirements and inspection criteria for each class of processed product, inspection is carried out to ensure that sanitation is adequate, approved formulations are followed, only wholesome ingredients are used, products are produced in accordance with approved production procedures, and products are truthfully labeled. Inspectors have the authority to prevent adulterated products from entering commerce and to condemn any such products they discover at a processing facility.

Total Quality Control

Some processing plants operate FSIS-approved total quality control (TQC) systems. TQC places on industry the responsibility for compliance with Federal laws and regulations and for producing safe, wholesome, and accurately labeled products. However, FSIS still verifies compliance.

FSIS requires that plants include 13 features in their TQC systems. These include:

1. General plant procedures from receiving to shipment of finished product;
2. List of plant management personnel;
3. List of raw materials and nonfood compounds received by the plant;
4. List of products produced by the plant categorized by classes that meet specific controls to meet Federal meat and poultry inspection regulations;
5. List of Federal regulations applicable to plant operations;
6. Identification of hazards and control points pertaining to the processing of each product;
7. Adequate records;
8. Policy on handling of inedible materials;
9. Cleaning procedures;
10. Monitoring system;
11. Corrective action procedures;
12. Statistical procedures; and
13. Plant profile.

The plant profile (item 13) includes, but is not limited to, information on slaughter or processing operations conducted, the use of outside contractors for specific operational functions, plant laboratory capabilities, waste disposal, clean-in-place systems, continuous processing systems, the use of consultants or outside laboratories, water potability certification, the sources of meat or poultry, suppliers, and recall procedures.

Performance Based Inspection System

The Agency began approving industry-developed TQC systems on a voluntary basis in the late 1970s. The use of TQC monitoring techniques by FSIS led in the 1980s to the implementation of an Inspection System Work Plan (ISWP) for those establishments that were not under an approved TQC plan. Both TQC and ISWP depended on the industry's acknowledging and taking responsibility for producing safe products and for maintaining operational controls in processing operations. The Performance Based Inspection System (PBIS) is an automated management system, managed by FSIS, that builds on TQC and ISWP and improves the documentation of inspection findings.

PBIS includes four components: a plant-specific monitoring plan developed from an Inspection System Guide (ISG); a plant profile, similar to the plant profiles developed for TQC; an automated system to schedule inspection activity and record inspection findings; and a Corrective Action System (CAS). PBIS enables FSIS to document findings on an inspector assignment schedule; document deficiencies and corrective action taken on a process deficiency record (PDR); and discuss deficient findings with plant management at the conclusion of an inspection visit. Agency personnel maintain PBIS schedules and findings.

The ISG is a uniform reference guide used by inspectors to ensure that establishments are meeting required standards of compliance. The ISG lists standards, references, and inspection tasks by process and provides for uniform evaluation and verification tests.

CAS is designed to cover the range of plants the Agency must inspect — from marginal to superior in compliance. It helps the Agency take prompter enforcement actions than in the past.

Summary

Traditional inspection has relied primarily on visual observations for diseased animals. New technologies have introduced rapid tests and diagnostics to identify conditions that make meat and poultry unfit for human consumption. In addition, FSIS has established programs that make industry more accountable for controlling its production process and quality assurance, so Agency inspectors can concentrate their efforts on industry oversight and verifying that food safety problems have been identified and corrected.

The Agency believes the introduction of HACCP into inspection operations would follow this same course and philosophy. In a HACCP system, FSIS believes industry would be responsible for developing and implementing its HACCP program, while FSIS would monitor and verify that industry is controlling its food production process. Emphasis will shift from detection to prevention of food safety problems.

B. Hazard Analysis and Critical Control Points

Hazard Analysis and Critical Control Points (HACCP) is a logical, simple, but highly specialized system of food safety control. It is designed to prevent the occurrence of public health problems by ensuring that controls are applied at any point in a food production system where hazardous or critical situations could occur. Hazards could include chemical, microbiological, or physical adulteration of food products. HACCP is intended to provide optimal control of food manufacturing to protect public health.

The HACCP system has been endorsed and recommended for adoption by Government and industry by the National Academy of Sciences/National Research Council (NAS/NRC) Committee on the Scientific Basis of the Nation's Meat and Poultry Inspection Program, by the NAS/NRC Committee on Food Protection Subcommittee on Microbiological Criteria and by other scientific experts. These experts recognize HACCP as a rational, improved approach to food production control that emphasizes those areas where control is critical to the manufacture of safe, wholesome food (NAS/NRC, 1985a, 1985b). FSIS is committed to the HACCP system because the system is scientifically based and because it is potentially applicable to the full range of critical consumer protection issues before FSIS.

FSIS believes that implementation of HACCP will benefit consumers, the industry, and the Agency itself by: (1) focusing inspection and industrial quality control activities on critical areas of product safety, wholesomeness, and the prevention of adulteration; (2) focusing industry actions on, and regulatory verification of, the production of safe and wholesome food; and (3) strengthening the scientific basis of inspection operations.

HACCP is a systematic approach to food safety and wholesomeness that is based on the following seven operational principles recommended by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF, 1989):

1. Assess hazards and identify prevention methods at each step of the food chain;
2. Determine critical control points. (A critical control point is any point where a hazardous product may result if the process goes out of control.);
3. Define requirements at each critical control point;
4. Establish procedures for monitoring each critical control point;
5. Determine corrective actions for deviations at each critical control point;
6. Establish effective recordkeeping and documentation; and
7. Determine verification procedures for the HACCP system.

C. HACCP Implementation Study

The Agency has set as a long-range goal the mandatory implementation of HACCP in all meat and poultry inspection activities. In 1989, FSIS Administrator Dr. Lester Crawford formed a HACCP Core Team and Steering Committee to lead the HACCP Implementation Study. In January 1990, the Core Team began a 2+-year study to determine the process for HACCP implementation. The study includes four stages:

1. Consultations and public hearings to solicit the views of FSIS employees, the public, academia, consumer groups and industry;
2. Workshops with industry held to ensure mutual understanding of HACCP and to develop model HACCP plans for specific products and processes;
3. In-plant testing; and
4. Evaluation of the study.

During the first stage, consultations were held from January through July of 1990 and yielded comments on the following topics:

1. Selection of specific products and processes as subjects for workshops to develop model HACCP plans;
2. Objectives and format for the workshops;
3. Role of the FSIS Special Team — seven Agency employees with strong backgrounds in all areas of inspection who will direct the workshops, in-plant training and testing and evaluation;
4. Selection of volunteer plants for in-plant testing of model HACCP plans;
5. Criteria for evaluating model HACCP plans and the effectiveness of HACCP;
6. Follow-up with interested parties during and after the study;
7. Reporting and disseminating the study's conclusions; and
8. HACCP training needs for both FSIS inspectors and industry personnel.

In the second stage, FSIS will sponsor five workshops to develop model HACCP plans for the following products: ready-to-eat refrigerated foods (such as "Keep Refrigerated" uncured products in sealed containers), scheduled the week of February 25, 1991; cooked sausage, scheduled the week of May 20, 1991; poultry (young chickens) slaughter, scheduled the week of August 26, 1991; fresh ground beef, scheduled December 1991; and swine slaughter, scheduled March 1992. Workshops may be convened for 1 to 5 days.

The FSIS Special Team will facilitate the workshops which are attended by industry technical experts. Workshops are open to the public. The model plans will identify critical control points (CCP's) and methods for controlling, monitoring, and verifying control at CCP's. The participants in each workshop will establish a steering committee that will be responsible for refining the generic HACCP plans in cooperation with the Special Team. FSIS also has selected "subject matter experts" (SME's) from Agency in-plant inspection employees who will provide technical expertise and guidance on the specific products or processes that are the subject of the workshops.

Prior to the testing of the model HACCP plans, FSIS will conduct brief "site evaluations" of the volunteer plants, checking layout, facilities, processes and products, and determining what adaptations of the HACCP model plans are necessary to make them compatible with specific plant situations. If necessary, the Special Team will reconvene the workshop steering committees and discuss any plant-specific refinements of the HACCP models. Plant-specific HACCP plans will then be developed. In each plant, the Special Team will work with plant employees and FSIS inspection personnel to familiarize them with HACCP principles.

There will be three phases of data collection during the testing of the model HACCP plans. First, baseline data will be collected by FSIS for 3 months prior to implementing the plant-specific model. Second, there will be an implementation phase of the plant-specific HACCP models in three volunteer plants for each product type. FSIS intends to select plants of differing sizes and complexity of operations. During this phase, which will last 3 or more months, plant personnel will adjust to the new pattern of HACCP operations, find and correct process control discrepancies, and alter the system, where necessary. FSIS intends to share the baseline and implementation data with plant management.

Third, the operational phase, begins when the Agency and plant management agree the HACCP system is implemented and ready to be operational. The operational phase will last 6 months and the data collected by FSIS personnel will not be shared with the plant until the final report. FSIS inspection during the implementation and operational phases will be conducted according to the model HACCP plans and by traditional inspection practices.

During the study, processing plants will continue to operate under PBIS. The CCP's for a plant's process will be entered into the PBIS system to be integrated into the assignment of inspection tasks. PBIS will assign priorities as indicated in the HACCP plan.

D. HACCP and Total Quality Management

HACCP complements other inspection systems. HACCP will coexist cooperatively with plant-operated quality control systems, with PBIS, and with other management initiatives.

One such initiative, Total Quality Management (TQM), is part of a Government-wide commitment to sustained continuous improvement in the quality and delivery of services to the public. TQM requires the combined efforts and involvement of all echelons of an organization: top management support, long-term strategic planning, employee training and recognition, and employee empowerment and teamwork. It encourages measurement and analysis of products and processes, and quality assurance — including the use of statistical process controls, where applicable.

The HACCP concept demands careful attention to process controls and facilitates continuous improvement in plants where it is applied. The planning for HACCP presupposes a gradual, long-term implementation, with provision for learning and continual improvement. Training and workshops are presupposed for both members of industry and Agency employees.

The HACCP consultations and public hearings have been provided to elicit the views of all concerned parties — consumers, the regulated industry, FSIS employees, and scientific experts. FSIS Administrator Dr. Lester Crawford has sought the views of Agency employees. FSIS has involved employees in the HACCP study by selecting a Special Team which is composed largely of persons with extensive field experience. For technical guidance in the implementation of HACCP in various process and product environments, FSIS has also selected "subject matter experts" (SME's) from the in-plant field inspection force. Industry commitment and involvement, plus training, teamwork and employee empowerment are driving forces for HACCP-based inspection.

As part of the HACCP implementation study, FSIS will evaluate the HACCP implementation process and the testing of the HACCP model plans developed in the workshops. The evaluation is an analytic study (See Deming, 1950, 1975) in that its purpose is to investigate changes to production and inspection processes that are intended to improve these processes in the future. The purpose of the evaluation is to assess, through quantitative and qualitative analysis, the manner and extent to which the Agency's HACCP initiative achieves its goals or produces other significant effects. An FSIS Evaluation Team, under the direction of the Core Team, will evaluate the HACCP Study. The leader of the Evaluation Team is Mr. Mark Manis, Assistant Executive Director of the HACCP Core Team.

A. Evaluation Plan

1. Evaluation Goals

The evaluation of the HACCP study has been designed around five specific goals. These goals are:

1. To evaluate the pre-implementation stages of HACCP models in the volunteer plants;

2. To evaluate the conformance of the generic HACCP models and the plant-specific HACCP models with the NACMCF HACCP principles;

3. To evaluate the functioning and effectiveness of the plant-specific HACCP models in the volunteer plants;

4. To evaluate the functioning and effectiveness of a HACCP-based inspection system in the volunteer plants; and

5. To evaluate the potential impact for nationwide implementation of a HACCP-based inspection system in meat and poultry plants.

To achieve these goals, an interdisciplinary team within FSIS will carry out a series of analytic studies. This approach will allow for in-plant testing of the HACCP plans in nine plants. Areas of strength and areas in need of improvement will be identified.

2. Methodology

In the 2+-year HACCP study, FSIS will apply the seven principles recommended by the NACMCF in several different settings. Generic HACCP models are being developed in workshops for ready-to-eat refrigerated foods, cooked sausage, poultry slaughter, fresh ground beef, and swine slaughter. These generic models, as adapted to particular plant circumstances, will be implemented in volunteer plants. Because it is feasible to test the models in only a few plants, the analytic study is considered the best approach to evaluating the models.

FSIS has identified 10 evaluation tasks to achieve the goals of the evaluation. Six of these tasks are being peer-reviewed. The evaluation tasks include:

Peer-reviewed	Not Peer-reviewed
HACCP Model Checklist	Workshop Evaluation
National Profiles	Training
Quantitative Plant Data	Economic Impact
Qualitative Plant Data	Staffing
Literature Review	
Inspector and Plant Personnel Survey	

Information related to the first goal of the evaluation program, the evaluation of the pre-implementation stages of the HACCP models, will be obtained from the workshop, training, and staffing evaluation tasks, which are not being peer-reviewed.

Information related to the second goal, the assessment of the generic and specifically adapted HACCP models, will be obtained from the HACCP model checklist task.

Information related to the third goal, evaluation of the functioning and effectiveness of the HACCP models applied in the volunteer plants, will be obtained from the quantitative plant data, on-site review and survey tasks.

The goal of evaluating the functioning of the inspection system in HACCP plants is the aim of the staffing evaluation task, which is not intended for peer-review, and the on-site review and surveys, which are.

Finally, all evaluation tasks, including the economic impact analysis and literature review, contribute to assessing the feasibility of a more general implementation of HACCP-based inspection beyond the volunteer plant situations.

FSIS will collect volunteer plant data in three phases. First, the Agency will collect baseline data on microbiological, physical, and chemical factors at various processing points for 3 months prior to implementing the plant-specific HACCP models. FSIS will collect the same categories of data at the same points for 3 or more months during the implementation of the HACCP plan. Finally, after the volunteer plant and the Agency agree that plant operations under HACCP are proceeding routinely, data will be collected during a third, operational evaluation phase lasting 6 months. The baseline, implementation and operational evaluation data will be analyzed and compared at the end of the testing period.

As an illustration of how achieving task objectives contributes to realizing the evaluation goals, consider the HACCP model checklist task. The task objective is to develop a method to assess the conformance of the model HACCP plans and the plant-specific HACCP plans to the seven HACCP principles recommended by the NACMCF. To accomplish the task, a checklist has been developed to obtain information principally on whether the features essential to any HACCP model are present and implemented. The results obtained will help assess the HACCP models being tested and establish the means of assessing HACCP systems in the future. A more thorough discussion of the relation between the objectives of individual tasks and the evaluation goals occurs later in this document.

FSIS will use several methods and sources of data collection to meet the study goals. This approach, known as triangulation, is used to gain an understanding of a phenomenon by examining the objective from more than one independently based route. In this case, quantitative data will be collected at CCP's, at control points (CP's), and on the final product. A literature review will be conducted to provide insight into HACCP concepts and implementation. Various types of qualitative data will also be obtained. FSIS will conduct interviews with inspection staff and plant personnel involved in the tests. Experts will conduct on-site reviews of the volunteer plants to collect data and observe plant activities. Together, these data collection efforts will ensure a complete and accurate picture of effects of the in-plant HACCP model and activities in the volunteer plants. Through the process of triangulation, FSIS will avoid over-dependence on the validity of any one source.

3. Use of Evaluation Results

The evaluation results from the in-plant test stage will serve an important role in informing decision-makers concerning any subsequent national level initiative. While these data should prove extremely useful in planning subsequent work, caution is urged in generalizing to the total plant population because of the small number of volunteer plants, the heterogeneity of the total plant population, and the dynamic nature of the test program, among other reasons.

B. Data Collection and Analysis

1. Role of Data Collection and Analysis

The collection and analysis of quantitative data are important to evaluate the HACCP models as implemented in volunteer plants. Data collected will include monitoring data at CCP's, evaluation data at CP's and verification data on finished product.

The plans and ideas for collecting and interpreting data are preliminary for two reasons. First, information needed for specificity, such as monitoring requirements of the HACCP models, is lacking at this point. Second, experience with application of the evaluation plan in early stages of the study may provide information useful for improving the plan.

The evaluation is intended to be an analytic study (see Deming, 1950, 1975). Its purpose is to investigate changes to production and inspection processes that are intended to improve future processes.

2. Data Collection

As previously mentioned, the duration of the HACCP test — the implementation and operational evaluation phases — in each plant will be at least 9 months; these phases will be preceded by a 3-month period in which baseline data will be collected. Baseline data will provide part of the background perspective needed to evaluate the impact of the HACCP models. The baseline period will serve to familiarize data collectors with collection procedures and get plant personnel accustomed to the presence of Agency personnel involved with the study.

Three of the five product types will be evaluated by FSIS and then peer-reviewed. These include ready-to-eat refrigerated foods, cooked sausage, and poultry slaughter (young chickens). FSIS will select three volunteer plants for each product to test the HACCP models. Qualitative data will be collected on characteristics of volunteer plants for use in the evaluation. (FSIS will test and evaluate the HACCP models for the other two products — fresh hamburger and swine slaughter — but time constraints do not allow them to be subject to peer review.)

Quantitative data will be collected from at least three different points and for a range of purposes:

- *Monitoring data on CCP's*
  These data will be used to evaluate the plant's capability to control its processes and the adequacy of the monitoring frequency specified in the HACCP model. The data will be collected by special in-plant data collectors (IPDC's) — FSIS personnel who are not normally assigned to the plant. Through all the testing phases, the samples and data will be collected by the same IPDC for each test plant. In addition, an attempt will be made to ensure that the FSIS inspection personnel regularly assigned to the plants during the three testing phases are the same individuals.

- *Evaluation data at CP's*
  These data will be used to investigate whether the model has identified the right CCP's, whether it includes too many or too few, and whether controls at the CCP's are effective. The data will be collected by the IPDC. When appropriate, results obtained by plant employees will be compared with those of Agency personnel.

- *Verification data for finished product*
  These data, which are also to be collected by the IPDC, will contribute to evaluating the overall effectiveness of the HACCP model. The data will demonstrate the consistency and level of plant performance and help to identify problems with the implementation of the model in the plant.

During the baseline period, data must be collected in a way that ensures comparability with data to be collected during the implementation and operational evaluation phases.

The factors to be examined — microbiological, chemical, and physical — will be safety related and will yield two types of quantitative data: measurements and counts. Examples of these data types include temperature measurements and number of carcasses with gross fecal contamination (a condition also to be gauged using bacteriological data).

FSIS will collect data periodically for the duration of the study. The number of tests to be performed on a factor will be decided on the basis of FSIS experience. It is generally agreed among quality control experts that 30 to 50 observations are needed on a process to evaluate its stability; FSIS will aim for approximately this number of observations. To evaluate the adequacy of a monitoring frequency specified in a HACCP model, FSIS will test at a rate more frequent than the model specifies. This requirement may increase the number of observations above 50.

These guidelines apply to measurements or counts:

- *Measurements*
  For investigation of process control, FSIS will test a number of specimens at each data collection time (e.g., a number of packages of finished product). FSIS will require at least five (five is the number most commonly used for this purpose).

  For the purpose of estimation, sample size formulas for measurement data can be found in any elementary statistics text but, at this point, information is not available to apply the formula. To the extent feasible within time constraints, FSIS will check the adequacy of initial plans by using information from the baseline period to show how precise the estimates provided by testing at the planned level will be.

  The efficiency and consistency of evaluations involving laboratory tests will be improved by arranging, where possible, for the tests for the three products to be done in the same laboratory. Doing microbiological (or chemical or serological) tests for a given plant in a single laboratory will eliminate between-laboratory variation from in-plant evaluations. The efficiency of comparisons will be improved by paired testing; i.e., collecting data before and after a control point from the same batch of product. Cause-and-effect investigations also will be facilitated by collecting information (both quantitative and qualitative) on the same batches of product.

- *Counts*
  For investigation of process control, FSIS will examine a number of specimens at each data collection time (e.g., a specified number of carcasses). The number chosen must be large enough so that one can expect to observe at least one defective in the group of specimens examined. For example, if one percent of processed birds have fecal contamination, 100 birds will be examined each time for the purpose of process monitoring. This rule will be followed in all cases where it yields a feasible sample size. Information on the percentage of defective processed birds that is collected in the baseline period will help to set appropriate sample subgroup sizes.

Data collection procedures will be consistent during the study, and will follow sampling protocols established before the study begins. The baseline period will serve as a pretest for protocols.

3. Data Analysis

Evaluation of overall study results will be aided by statistical analyses of the quantitative data collected. Techniques that will be used include:

- *Statistical Quality Control Techniques*
  FSIS will use run charts and control charts to evaluate the stability of process variation for such items as plant control of a monitoring factor at a CCP, before/after differences at a CP and final product characteristics. The purposes will be to look for sustained consistent performance and to determine process capability. The charts produced will serve as graphical aids to the presentation of data.

- *Summary Statistics*
  The extent to which results can properly be summarized and the manner in which they are presented will depend on the outcome of the analyses of process stability. The summaries could include histograms, box plots, means, standard deviations and percentiles. Tests whose results yield yes/no or other binary results will be summarized in terms of percent positive and related statistics.

- *Cause-and-Effect Analysis*
  The statistical analysis will be directed toward measuring the effect of the HACCP program on the characteristics of the end product. Deviations from the expected end result should be explained by an event which affected a CCP or CP. Causal analysis will be appropriate if, for example, the analysis of the stability of final product-safety characteristics shows variations from the desired characteristics. An effort then will be made to relate the effect to relevant in-process quantitative data or to qualitative data collected during the study and to identify possible causes. Results of the analysis could lead to revision of the HACCP model. Techniques used will depend on the findings.

C. Focus of Evaluation Tasks

1. Task Interrelationships

The evaluation tasks for the in-plant testing stage of the HACCP study are directed at evaluating the operation of HACCP systems in the production environment and the functioning of the FSIS inspection system in the HACCP environment. The tasks reflect the concern of the Evaluation Team and the Agency that HACCP be applied in a manner that conforms to the best scientific understanding of the concept and that the results from applying HACCP models be identified and correctly evaluated.

The tasks relate to the HACCP concept, data collection, data analysis and comparison. For example, there are tasks to collect quantitative data before and during the tests. Another task is aimed at developing national profiles on plants according to characteristics that may be useful as a basis of comparison with the volunteer plants. The characteristics that may be applicable are plant size or volume, kind of product manufactured, plant performance, and other characteristics that may be described quantitatively through the use of data from PBIS and other Agency sources. FSIS will have at its disposal national profiles on a variety of plant and product characteristics. The Evaluation Team should be able to make observations and comparisons of similarities and differences between the conditions in the volunteer plants and the patterns shown in the national profiles.

Other comparisons will be possible between data collected in the volunteer plants during the baseline period and those collected during the test period. FSIS will also observe the patterns in the data collected for the various physical, chemical, and microbiological factors. In choosing the factors and the points where data are to be collected, care has been taken to minimize reference to the CCP's likely to be selected for the HACCP models. For this reason, FSIS will have a set of reliable measures of changes that may occur in the plant during the test period.

The quantitative evaluations of the plant environment and HACCP systems will be balanced by qualitative observations. These observations, including general housekeeping, employee practices, and management capabilities, can be used to complement, balance, or explain the quantitative observations.

Further results, based on surveying inspectors and plant personnel, may provide even more direct evidence on the functioning of HACCP systems and inspection operations than can be gleaned from laboratory results. This information can also provide a practical, or operational, dimension to complement the study of the conformance of the generic and plant-specific HACCP models to the NACMCF principles.

As to the HACCP model evaluation, the volunteer plant experiences will provide the opportunity for the HACCP models to be adjusted according to circumstances. It is important that such adjustments as are permitted conform with HACCP principles. At the same time, the tests will provide an occasion for the Agency to deepen its understanding of those principles in application.

FSIS is also interested in comparing its understanding and implementation of HACCP to those of others in the scientific community. Through the literature review task, the historical and technological aspects of HACCP will be explored, and the regulatory implications highlighted.

2. Evaluation Tasks, Objectives, and Methods

The following is a brief review of evaluation tasks to be peer-reviewed. (A detailed description of each task, its objectives, sampling plan, and analytical methodology can be found in Part Two.)

HACCP Model Checklist Task
The objective of the HACCP Model Checklist task is to develop a method for assessing the conformance of the model HACCP plans — both the generic and plant-specific models — with the NACMCF principles. This objective is identical with the second goal of the overall evaluation. In pursuit of this objective, FSIS will evaluate the HACCP plans developed in the workshop with the aid of a 50-item checklist (see Appendix A). The checklist is based on the NACMCF guide for HACCP implementation, and addresses the control of physical, chemical, and microbiological hazards. For a generic or plant-specific model to be evaluated as in conformance with HACCP principles, all applicable checklist questions must be answered in the affirmative.

National Profiles Task
The objective of the national profiles evaluation task is to identify seven health and safety factors in those meat and poultry plants producing ready-to-eat refrigerated foods,

cooked sausages, and young chickens. National profiles of these seven factors will be used to present an overview of the general plant population from which the volunteer plants will be selected.

The seven factors include:

1. Maintenance of facilities, equipment, water supply, and sewage disposal;

2. Sanitation and pest control;

3. Control of purchased materials;

4. Control of processing and production;

5. Finished product inspection;

6. Control of condemned and inedible materials; and

7. Handling, storage, and shipping of finished products.

Information on the same factors is to be collected in the volunteer plants during the testing of HACCP models.

The data from which the profiles are to be generated are contained in the PBIS and other Agency data bases. Information on plant profiles, the results of ISG tasks, and corrective actions are contained in the PBIS database. The results of audits performed by Agency program reviewers and evaluators are contained in the Review and Evaluation Information System (REIS). Information from a special FSIS refrigerated foods survey conducted during 1990 is available separately, as are the monthly production data showing the condemnation rates of slaughtered young chickens.

FSIS will use data from these sources to determine the population of meat and poultry establishments producing ready-to-eat refrigerated foods and cooked sausages, and poultry plants slaughtering young chickens. The general characteristics for plants of the appropriate size and production volume will be determined for each product category. FSIS also will collect data relating to safety and health activities for each product category and reported according to size and volume characteristics.

Data will be charted to show the distribution by plant size and volume in relation to health and safety factors. Data will be presented by methods sanctioned by the American Society for Quality Control. The data sources used in developing the national profiles will also be available for use in the volunteer plant data evaluation task. The national profiles task is expected to provide background information that will be of value as the Evaluation Team strives toward its third major goal, the evaluation of the functioning of plant-specific HACCP models in volunteer plants.

Quantitative Plant Data Task

As previously mentioned, quantitative data on in-plant testing will be collected in the volunteer plants during a baseline period, Phase I, and during the implementation and operational phases — Phase II and Phase III — of the testing. The results of the data collected during the implementation of HACCP models will be compared with the baseline data. Phase I and Phase II data collected by the Agency will be shared with the test plants to assist them in the implementation of the HACCP models. (Phase III data will not be shared with the plants until the final report and analysis are completed.) When appropriate, plant data will be used in addition to those collected by the Agency.

The objectives for the volunteer plant testing are: (1) to develop a list of factors (physical, chemical, and microbiological) to be evaluated at CCP's, CP's and on finished product; and (2) to develop sampling criteria for each of the factors. After the data have been collected and summarized for each of the factors, FSIS will have partially reached its goal of evaluating the plant-specific HACCP models in the volunteer plants. The complete evaluation will include information from the national profiles to be developed, the qualitative plant data, and the survey of plant personnel.

FSIS has identified the factors (microbiological, chemical and physical) to be evaluated without reference to the HACCP models because they had not been developed at the time the Evaluation Plan was written. FSIS also has developed methods for evaluating the factors. Examples of microbiological factors are aerobic plate count, coliforms, and *Listeria* species; some chemical factors are pH and chlorine concentration in processing water. Physical factors for processed products include product temperature, storage temperature, and package integrity. For young chicken slaughter, physical factors include product handling and the presence of fecal contamination on carcasses.

FSIS chose the factors on the basis of their relation to health and safety and decided on the methods to be used in gathering and analyzing data on the factors. Once the HACCP models for the products being studied have been developed, a further assessment will be made on the appropriateness of testing for each factor at specific CP's.

Microbiology testing will include indicator organisms such as aerobic plate count, coliforms, and *E. coli* which are essential to HACCP evaluations and have been selected for use for both raw and cooked product. These organisms can easily be quantified and are expected to occur at sufficient frequency and at a sufficient level to limit the number of samples required to be analyzed and to provide a measure of difference within critical control points of a HACCP system.

For pathogenic organisms, such as salmonellae, the analytical procedures are difficult and time consuming and, because of this, are often not used to enumerate the number of organisms present in a sample. Furthermore, the levels of pathogenic organisms in samples and numbers of samples that are positive are often very low. In ready-to-eat product, for example, the frequency of occurrence of salmonellae is less than 1 in 1,000 samples, and when positive, the levels are very low. The number of samples required to show a difference before and after or to evaluate process control would be very large. In raw product such as chickens, the levels of salmonellae are often less than 30 organisms on a whole carcass. It is difficult to demonstrate a difference at these low levels even with large sample sizes. For these types of product, the aerobic plate count or other checks for indicator microorganisms are better.

The HACCP Peer Review panel recommended FSIS collect data on the number of salmonellae for ground beef, poultry slaughter, and swine slaughter products/processes during the in-plant testing phase. Further, the peers recommended that data regarding salmonellae be kept confidential or should otherwise not be collected. The agency believes data can be maintained as confidential from public requests during the course of the study, therefore, salmonellae enumeration data will be collected for the three topics as recommended by the peers.

FSIS will collect microbiology samples at selected locations along processing lines and on finished products. Analysis will be conducted according to standard methods described in the Agency's Microbiology Laboratory Guidebook.

Chemistry tests will be those presented in the Agency's Chemistry Laboratory Guidebook or in the 15th edition of the Association of Official Analytical Chemists (AOAC) methods. Some factors selected for testing (e.g., salt) will provide indirect measurement information on the microbiological or chemical safety of the product or process. For example, the presence of salt is not a health hazard but helps to prevent microbial growth. The appropriateness of certain chemistry tests will be decided once specific "keep refrigerated" or cooked sausage products are identified for sampling.

Physical factors selected for observation in the processing environment include both plant-performed and FSIS inspection activities. These factors will be evaluated to determine the effectiveness of inspection in the volunteer plants before and after the HACCP models are implemented. Physical factors chosen for the young chicken slaughter environment are related to manufacturing processes and controls. They reflect conditions in the areas of sanitation, contamination, and product handling.

Specific instructions on the methods for selecting samples and sample handling will be provided for FSIS data collectors to control bias in sample selection over the test period and across plants. The methodology for each factor and product is in Part Two of this document.

Qualitative Plant Data Task

The objective of the qualitative plant data task is to identify factors or criteria that will provide an overview of volunteer plant environments, management capabilities and willingness to control the manufacturing process, and management attitudes and commitment to quality and regulatory compliance for health and safety. Also, this task will help explain evaluation findings and suggest improvements. Volunteer plants will be evaluated by assessing 11 factors. The factors are:

1. General housekeeping;
2. Condition of facilities;
3. Employee hygiene;
4. Employee sanitary practices;
5. Employee attitudes toward inspection requirements;
6. Employee training;
7. Management supervisory attitudes;
8. Management response to problems;
9. Management strategies to prevent contamination hazards;
10. Product quality; and
11. Management programs and systems.

A data collection instrument (see Appendix B) has been developed to gather on-site information about the plants participating in the HACCP in-plant tests. FSIS will use the instrument to determine the degree to which conditions meet or exceed Agency standards. The answers to the questions are weighted to allow for judging degrees and making distinctions. The instrument also provides for narrative responses to record observations and comments and to document specific activities about how management programs and systems in the plant affect product quality.

Four persons from the Agency's headquarters staff will be selected as data collectors who will use this instrument. Their selection will be based on: their overall knowledge of and experience in inspection and the meat, poultry, and meat processing industries; scientific expertise in food technology and related disciplines; and capability to perform evaluations and communicate the results. They must be able to identify health- and safety-related factors in the production environment and managerial attitudes that affect product safety and public health. Each data collector will be assigned to complete the instrument twice for one volunteer plant during the period of the evaluation (once during the baseline phase and once at the end of the operational evaluation phase).

After they are selected, the data collectors will be trained in the intended use of the instrument. Training will include an initial briefing to present the objectives of the instrument in

relation to the overall HACCP Evaluation Plan and to provide an overview of the rationale for the instrument. Hypothetical situations involving use of the instrument will be considered and the data collectors will be brought to a common understanding of how to respond to specific items on the data collection instrument. The rest of the training, involving practice in the use of the instrument, will be completed on-site in several meat or poultry plants. Correlation of data collection activities to ensure consistency of findings is critical to the validity of the data.

It is assumed that all plants in the project will meet USDA standards, at a minimum. Satisfactory compliance thus becomes the foundation or starting point from which HACCP-oriented improvements can be instituted.

The qualitative plant data are intended to provide a dimension and perspective complementing those provided by the quantitative data from the testing of HACCP models. The quantitative and qualitative evaluation tasks together will support the attainment of the third goal of the evaluation.

FSIS Inspector and Plant Personnel Survey Task
The objective of surveying FSIS inspectors and plant personnel is to obtain information from the two perspectives on the experience of implementing the HACCP model. FSIS will use two questionnaires, one for each of the two groups (see Appendix C and Appendix D). To the extent possible, Agency personnel will administer the questionnaires through in-person interviews. Interviews will be conducted with inspectors, inspectors in charge (IIC's), circuit supervisors (CS's), and plant officials. In the infrequent case when it is not possible to conduct in-person interviews, the questionnaires will be administered by mail or telephone.

The questionnaire for the inspectors covers such topics as the criteria in use at CCP's, monitoring of CCP's, plant management activities, and working relations with plant personnel. The questionnaire for plant personnel covers such topics as CCP criteria, CCP monitoring, and working relations with inspection personnel. Data collection procedures and forms will be pretested to field-test the questionnaire and to minimize potential sources of bias. Information from the questionnaire, when analyzed, should provide valuable insights into the functioning of the HACCP models and the inspection system. The objectives of this evaluation task support both the third and the fourth goals of the overall evaluation.

Literature Review Task
The objectives of the literature review are several. They include documenting the evolution of the use of quality assurance features in food inspection to enhance the safety of meat and poultry products. FSIS expects this review to demonstrate the consensus of scientific opinion on the application of HACCP systems to food production. Another objective is to identify the advantages and disadvantages in using a HACCP approach in meat and poultry inspection.

The literature review will be wide-ranging, and will cover the whole experience of HACCP and quality assurance applications in food production, both nationally and internationally, from the early 20th century to the present. It will provide additional perspective on the HACCP model evaluation and on the functioning of the generic and plant-specific models, and will support the goals of the overall evaluation.

D. Limitations

The limitations of this study are related partly to the fact that the HACCP models are being tested in only a few volunteer plants. Thus, any generalizations of the results of the in-plant testing for a class of plants, products, or processes will have to be carefully qualified. Further, the characteristics of the available data and data sources, whether qualitative or quantitative, must be identified and taken into account before analysis can be completed.

General Limitations of Data Analysis
Limitations of the data analysis will not be clear until volunteer plants and their characteristics are known and the HACCP models have been developed and adapted to the volunteer plants.

One limitation known at this stage is that replication of plants with similar characteristics will not be possible, given the numbers of plants to be involved.

The Agency will be limited in its analysis if changes are made in a plant's HACCP program during the study. In particular, it will not be possible to evaluate a plant's capability to maintain controls under an altered system if there is little time left in the six-month study period at the point changes are made.

Limitations of data obtained in specific evaluation tasks may be described as follows.

Quantitative Plant Data
FSIS will conduct in-plant tests only in plants that have volunteered to participate. Inferences that extend beyond these plants are based on subject matter experts' professional judgment.

Baseline data will be collected in each volunteer plant for 3 months prior to a 6-month test period for the HACCP plan. It will not be possible, during the time period of the in-plant testing, to conduct tests for seasonal variations or other variables for which controls cannot be provided.

Testing will be conducted on the normal production system of the plants. It will not be possible to introduce anomaly batches or lots to ensure that all types of batches or lots are tested. It is assumed that, during the in-plant testing period, many different conditions of lots or batches will be encountered.

Qualitative Plant Data
Because only a limited number of on-site reviews are contemplated, it is possible that the analysis of qualitative plant data could be biased by day-to-day operational variability. While it is preferable that each plant be reviewed more than once during both "pre-HACCP" and "post-HACCP" data collection periods, resource constraints will prevent such frequent visits. As is the case with the quantitative data analysis, caution must be observed in extrapolating the results to a whole class of plants, processes, or products. Even so, it is expected that the qualitative data analysis will provide a useful adjunct to the results of the quantitative data task.

The data quality is dependent on the objectivity and expertise of the data collectors. To minimize variability in the data, three basic strategies will be used:

1. The same four data collectors will be used in all volunteer plants to make the qualitative assessment.

2. The same data collector will make both qualitative assessments in a given volunteer plant.

3. All data collectors will be thoroughly trained in the use of the instrument to ensure consistency in findings before they are sent to the plants.

While every effort will be made to ensure data quality and consistency, no conclusions will be based solely on the qualitative data. The narrative descriptions of observations will be used to explain and support the ratings on the focus issues.

The qualitative data will be carefully evaluated in relation to the totality of the data collected in each plant. The instrument is designed to elicit qualitative data that will provide a supplementary perspective and useful insight in the final evaluation on the use of HACCP in meat and poultry plants.

National Profile Data
Much of the data available for use in developing the national profiles was collected for other purposes and may complicate its use for the HACCP analysis. Sample collection in many cases was non-random and observations tended to be biased toward areas of noncompliance and lacked coordination between observers of similar phenomena. Also, national profiles will tend to reflect only the most recent production history because the most abundant data have existed only since the inception of PBIS (1988).

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Glossary of Terms

The Agency - The Food Safety and Inspection Service, U.S. Department of Agriculture

ADP - Automated Data Processing

AOAC - Association of Official Analytical Chemists

CAS - Corrective Action System - under PBIS, the procedures for following up on deficiencies identified by the FSIS inspector

CCP - Critical Control Point - any point or procedure in a specific food system where loss of control may result in an unacceptable health risk

Core Team - five FSIS staff members who provide leadership for the HACCP Study

CUSUM - Cumulative Sum - statistical method used in recording data on finished product evaluations

Deficiency classification guide - PBIS method for determining whether deficiencies are major, minor, or critical and hence what inspector reporting or corrective actions may be necessary.

FMIA - Federal Meat Inspection Act

FPS - Finished Product Standards - used in SIS

FSIS - Food Safety and Inspection Service

HACCP - Hazard Analysis and Critical Control Point - a logical, simple, but highly specialized systems of food safety control that is based on seven principles recommended by the NACMCF: (1) assess hazards and identify prevention methods at each step of the food chain; (2) determine critical control points (CCP's); (3) define requirements at each CCP; (4) establish procedures for monitoring each CCP; (5) determine corrective actions for deviations at each CCP; (6) establish effective recordkeeping and documentation; (7) determine verification procedures for the HACCP system.

IPDC - In-Plant Data Collector

ISG - Inspection System Guide - under PBIS, a document that summarizes all FSIS requirements, compliance standards, and inspection tasks to be performed in meat and poultry processing establishments.

ISWP - Inspection System Work Plan - a previous processed products inspection system which structured inspection activity through a plan of inspection.

MLG - Microbiology Laboratory Guidebook

MPI - Meat and Poultry Inspection

NACMCF - National Advisory Committee on Microbiological Criteria for Foods

NELS - New Line Speeds - poultry inspection system

Official establishment - a meat or poultry slaughtering or processing plant where Federal inspection is carried out

PBIS - Performance Based Inspection System - the automated decision-support system for administration and management of inspection of processed meat and poultry products. The system employs four inspection tools: a plant-specific monitoring plan based on the Inspection System Guide (ISG); a plant profile; an ADP system for scheduling inspection activity and recording inspection findings; and a corrective action system.

PCOLPQC - Poultry Carcass On-Line Partial Quality Control - a statistically based sampling system for assuring control of poultry processing operations

PDR - Process Deficiency Record - under PBIS, an official form used by the FSIS inspector to notify plant management of deficiencies and by plant management to notify the FSIS inspector of action taken to correct the deficiencies and prevent their recurrence.

PPIA - Poultry Products Inspection Act

PQC - Partial Quality Control - a voluntary plan or system for controlling a product, operation, or part of an operation

SIS - Streamlined Inspection System - most widely used inspection system for young chickens

SME's - Subject Matter Experts - Agency in-plant persons chosen for their experience and ability in certain specialized areas to provide technical advice and guidance in the development of HACCP models

Special Team - Agency employees trained to facilitate workshops

TQC - Total Quality Control - a voluntary, comprehensive, plant-wide system or plan for controlling products and processes in an official establishment

TQM - Total Quality Management - a strategic, integrated management system for achieving customer satisfaction which involves all managers and employees and uses quantitative methods to continuously improve an organization's performance

USDA - United States Department of Agriculture

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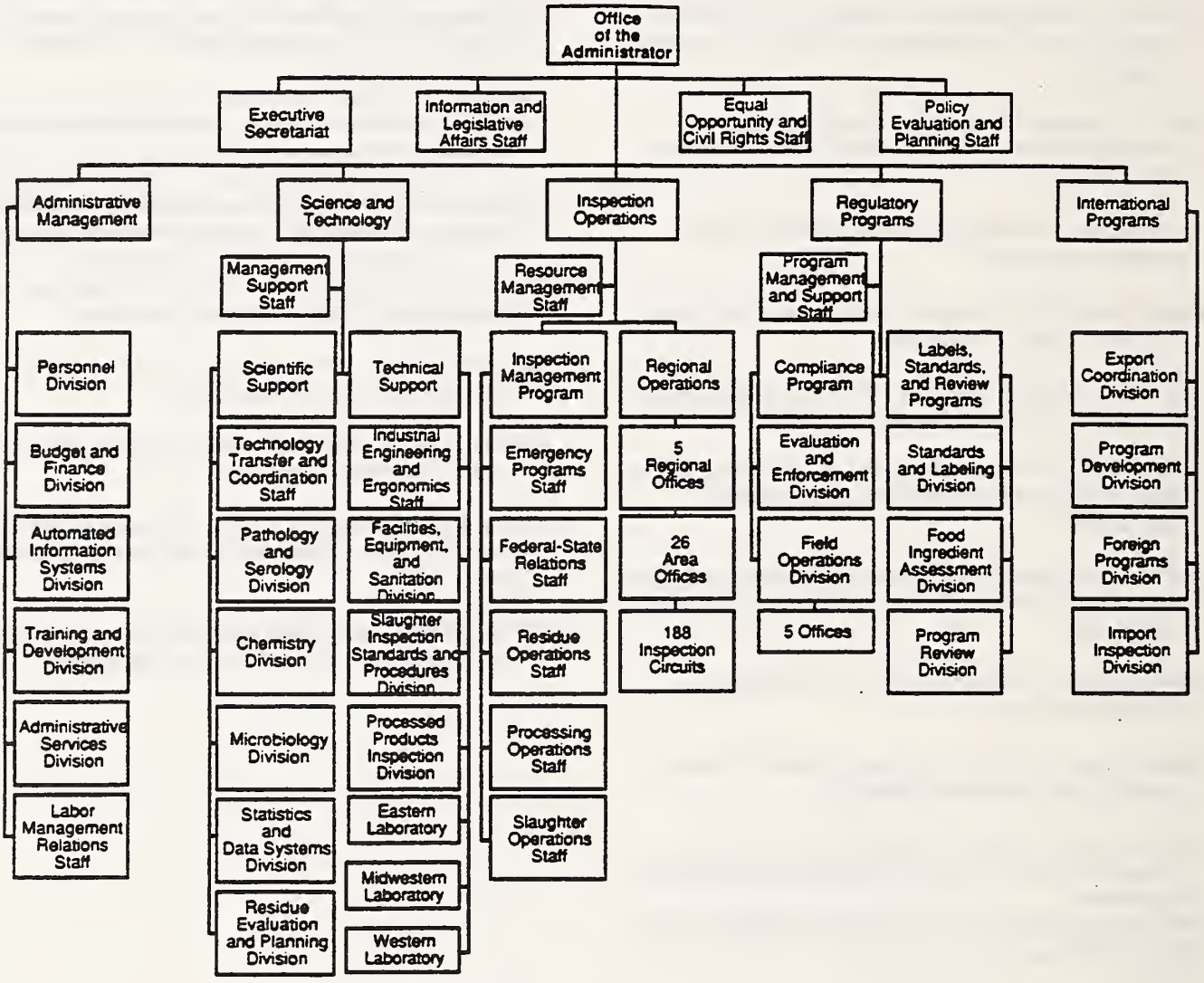
Food Safety and Inspection Service
Organizational Structure



Part Two
Protocols and Instruments

I. HACCP Model Checklist

Objective

To assess conformance of the model HACCP plans and the plant-specific HACCP plans to the principles recommended by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF).

Methodology

The NACMCF principles and implementation guide have been used to develop a checklist consisting of 50 yes/no questions to evaluate the degree to which each plan conforms to the principles recommended by NACMCF. Duplication of questions has been incorporated to weight for importance.

FSIS will use the checklist to evaluate the model HACCP plans developed in the workshops and the plant-specific HACCP plans. This evaluation will focus on the plan itself, not on its implementation. All applicable answers must be "yes" for the HACCP plan to be regarded as in conformance.

Objectives

To develop health and safety national profiles of meat and poultry plants producing ready-to-eat refrigerated foods, cooked sausages, and young chickens.

To use the national profiles as an overview of the general plant population from which volunteer plants will be selected. Information identical to the profiles will be collected on each volunteer plant during testing.

Methodology

FSIS will use the following data sources to develop national profiles.

Performance Based Inspection System (PBIS). PBIS contains four major components, including plant profiles (plant characteristics such as size, volume, management officials), the Inspection System Guide (a compilation of inspection tasks to measure industry compliance to inspection standards for all processing and allied slaughter activities), a Corrective Action System (procedures for correcting deficiencies), and an automated data support system that schedules inspection activity and records results of inspections performed by FSIS inspectors.

FSIS Review and Evaluation Information System (REIS). REIS records results of audits performed by FSIS Review and Evaluation officers in slaughter, allied slaughter, and processing establishments which are inspected by FSIS.

Special FSIS survey on refrigerated foods. FSIS conducted a special survey September through November 1990 to obtain information on the number of FSIS-inspected refrigerated foods plants and the types of refrigerated products produced.

FSIS monthly production data FSIS Form MP-513 (Poultry Inspection—Daily Summary). FSIS records the condemnation rates of slaughtered young chickens.

FSIS will use data from the above identified data sources to determine the population of meat and poultry establishments producing ready-to-eat refrigerated foods and cooked sausages, and poultry plants slaughtering young chickens. The special FSIS survey will be used to establish the population of refrigerated food manufacturers. Data from PBIS will be used to establish the population of meat and poultry cooked sausage producers, and data from FSIS Form MP-513 will be used to establish the population of plants slaughtering young chickens.

FSIS will determine general characteristics of plant size and volume for each product category. Size and volume characteristics for refrigerated foods and cooked sausages will be obtained from plant profiles in PBIS. Size and production volume characteristics for plants slaughtering young chickens will be obtained from FSIS Form MP-513.

The Agency will collect data relating to safety and health activities for each product category and report these data according to size and volume characteristics. Plant performance on safety and health activities will be collected from PBIS data sources for refrigerated foods and cooked sausages. Safety and health activities related to plants slaughtering young chickens will be collected from REIS.

Data on safety and health activities will be compiled for seven factors.

1. *Maintenance of facilities, equipment, water supply and sewage disposal.*

   FSIS requires pre-approval of all facilities, equipment, and operational environmental factors, including potable water and ice through certification of potability.

   FSIS will evaluate this factor by analyzing: inspections or audits performed on processing facilities; environmental temperature; temperature of hot water used for sanitizing; equipment maintenance; water and ice potability testing; chlorination of water supply (when non-municipal source is used); back-flow pressure controlling devices; and blueprints.

2. *Sanitation and pest control.*

   FSIS requires plants to maintain sanitary facilities and equipment. Additionally, FSIS requires plants to maintain separation of cooked and raw products and traffic between these areas, and acceptable pest control applications and compounds.

   FSIS will evaluate this factor by analyzing: inspections or audits performed on sanitation of equipment prior to the start of processing operations; sanitation of equipment during preparation and processing of products; plant employee hygiene practices; and the use and application of pest control.

3. *Control of purchased materials.*

   FSIS requires pre-approval and/or receipt of wholesome purchased materials and ingredients.

   FSIS will evaluate this factor by analyzing: inspections or audits performed on incoming materials and ingredients.

4. *Control of processing and production.*

   FSIS monitors the safe and wholesome production of processed products by performing inspection tasks at key points in the production system. In slaughter, FSIS monitors the wholesome processing of young chickens by performing tasks at key points in the slaughtering and processing of young chickens.

   FSIS will evaluate this factor by analyzing: inspection or audits at key slaughtering, processing, and production points such as ante-mortem and post-mortem inspection, chilling of poultry carcasses, processed products formulation, and cooking and cooling according to time/temperature standards.

5. *Finished product inspection.*

   Manufacturers are responsible for producing safe, wholesome, unadulterated, and properly labeled products. Sampling and acceptance inspection are performed as a means of determining that carcasses and products meet these requirements. Testing involves both on-site and laboratory methods.

   FSIS will evaluate this factor by analyzing: inspections; audits; on-site tests; poultry finished product standards; and laboratory analyses, such as testing for *Listeria* and *Salmonella* on cooked products.

6. *Control of condemned and inedible materials.*

   FSIS monitors the identification, segregation, and disposition of condemned animals; denaturing of inedible materials; and facilities for handling condemned and inedible materials.

   FSIS will evaluate this factor by analyzing: inspection or audits of the identification, segregation, disposition of condemned animals; denaturing of inedible materials; and facilities for handling condemned and inedible materials.

7. *Handling, storage, and shipping of finished products.*

   FSIS monitors the handling, storage, and shipping of finished products to ensure they are wholesome and safe until leaving the plant.

   FSIS will evaluate this factor by analyzing inspections or audits, such as those of temperature of storage units, packaging of finished products, and cleanliness of shipping vehicles.

Data will be presented by charts and graphs to show the distribution by small, medium, and large size and volume in relation to the seven health and safety factors listed above. For the most part, the data will represent decisions on the acceptability or nonacceptability of meat and poultry establishments, and on the regulatory compliance of the establishments. Data will be presented by methods sanctioned by the American Society for Quality Control. The same data sources will be used for the national profile as well as for the test plants.

Objective

To collect appropriate data for safety-related factors (physical, chemical, and microbiological) for evaluating the HACCP models for ready-to-eat refrigerated foods, cooked sausage, and young chickens. The data relating to the factors will be collected on CCP's, CP's, and finished product for the three products.

Methodology

The methodology includes a justification for each factor included in the test (as related to its safety implications), the analytical method (measurement) for the factor, the sample procedure, and instructions for handling samples. FSIS will provide the IPDC with specific instructions on the method for selecting samples and sample handling to control bias in sample selection over the test period and across plants.

FSIS developed a list of factors for the three categories that is as inclusive as possible for collection of baseline data. However, other factors may need to be added after the HACCP models for each product are developed. The appropriateness of testing each factor at a specific CCP or CP will be determined after the HACCP models are developed in the workshops.

Agency data collectors will collect the safety-related data as well as ancillary information including time of day, date, temperature, condition of product, shift, producer, etc. that may be useful in evaluating the conditions under which the tests are conducted.

Data will be collected for some factors during the entire test time period. Other factors may be tested during shorter, intensified data collection periods.

The methodology for in-plant testing is defined below. Factors (physical, chemical and microbiological) to be tested are listed for each product. The Agency intends to keep confidential the data collected in the 15 test plants until the HACCP Study and final report are completed. The final report will include an analysis of the plant data and Agency recommendations.

Microbiology

Microbiology samples collected at selected locations along the processing lines at the volunteer plants as well as samples of finished products will be analyzed microbiologically to establish bacterial profiles for each product.

Chemistry

The chemical tests are proposed to generate data to evaluate the HACCP system in the volunteer plants. References to the Association of Official Analytical Chemists (AOAC) methods are from the 15th edition except as noted otherwise.

Physical Processing

The physical factors include both plant-performed activities and FSIS inspection activities. These factors will be evaluated to determine the effectiveness of inspection in the volunteer plants before and after the HACCP inspection model is implemented.

Physical Slaughter

The factors were selected to capture information about the chicken slaughter manufacturing process and controls for that process. The factors focus on the problem areas of sanitation, contamination, and product handling. Factors have been limited to only those characterized as potential high risks to human health and safety.

The methodology for each factor and each product is defined in the following pages.

Microbiology

Microbiology Factor 1 - Refrigerated Foods – Aerobic Plate Count @ 35°C

Purpose: To compare profiles of total aerobic plate counts @ 35°C at selected locations and on finished product produced at volunteer plants prior to and after implementation of a HACCP plan.

Sampling Plan: Samples will be randomly selected at locations in processing areas prior to and after HACCP implementation.

Finished product samples from a processing line will be randomly selected for the time period specified prior to HACCP implementation and again after HACCP has been in operation.

Samples will be collected and shipped frozen to a FSIS Technical Support Laboratory according to Section 23B of The Meat and Poultry Inspection Manual until the FSIS Directive (microbiological sampling) becomes available.

Analytical Method: The method shall be that described in Section 3, Microbiology Laboratory Guidebook (MLG, 1974), modified by substitution of 3M Petri Film for APC enumeration (AOAC).

Microbiology Factor 2 - Refrigerated Foods – Aerobic Plate Count @ 20°C

Purpose: To compare profiles of total aerobic plate counts @ 20°C at selected locations and on finished product produced at volunteer plants prior to and after implementation of a HACCP plan.

Sampling Plan: See Microbiology Factor 1.

Analytical Method: See Microbiology Factor 1.

Microbiology Factor 3 - Refrigerated Foods – Coliforms

Purpose: To compare profiles of total coliforms at selected locations and on finished product produced at volunteer plants prior to and after implementation of a HACCP plan.

Sampling Plan: See Microbiology Factor 1.

Analytical Method: The method shall be that described in Section 3, MLG, modified by the substitution of Petri Film for enumeration of coliforms.

Microbiology Factor 4 - Refrigerated Foods - *Escherichia Coli*

Purpose: To compare profiles of total *E. coli* at selected locations and on finished product produced at volunteer plants prior to and after implementation of a HACCP plan.

Sampling Plan: See Microbiology Factor 1.

Analytical Method: The method shall be that described in Section 3, MLG, modified by the substitution of Petri Film for enumeration of *E. coli*.

Microbiology Factor 5 - Refrigerated Foods - *Staphylococcus Aureus*

Purpose: To compare profiles of total *S. aureus* at selected locations and on finished product produced at volunteer plants prior to and after implementation of a HACCP plan.

Sampling Plan: See Microbiology Factor 1.

Analytical Method: The method shall be the standard microbiological method contained in the MLG (1974).

Microbiology Factor 6 - Refrigerated Foods - Gas Forming Anaerobes (GFAs)

Purpose: To compare profiles of total gas forming anaerobes at selected locations and on finished product produced at volunteer plants prior to and after implementation of a HACCP plan.

Sampling Plan: See Microbiology Factor 1.

Analytical Method: See Microbiology Factor 5.

Microbiology Factor 7 - Refrigerated Foods - *Listeria* Species

Purpose: For evaluating the microbiological level of cleanliness of equipment during operations at selected locations in volunteer plants prior to and after implementation of a HACCP plan.

Sampling Plan: Swabs of equipment as part of preoperational sampling and of product that contacts non-food contact surfaces and equipment.

Samples will be collected and shipped frozen to a FSIS Technical Support Laboratory according to FSIS Directive (microbiological sampling).

Analytical Method: The method shall be the standard FSIS microbiological procedure described in Laboratory Communication 57, excluding speciation.

Microbiology Factor 8 - Refrigerated Foods - Species

Purpose: To detect in refrigerated foods the presence of unlabeled animal species that may cause allergic-type reactions in susceptible individuals.

Sampling Plan: Finished product samples will be collected prior to and after HACCP implementation.

Samples will be collected and shipped frozen to a FSIS Technical Support Laboratory according to FSIS Directive (microbiological sampling).

Analytical Method: The method shall be the standard microbiological procedure described in Laboratory Communication 58.

Chemistry

Chemistry Factor 1 - Refrigerated Foods - Chlorine In-Processing Water

Purpose: Some establishments use chlorine water spray or wash to reduce the microbial load of product before further processing. Appropriate controls consisting of calibration of metering devices, record keeping, and verification testing will be in place.

Sampling Plan: Samples will be taken at random times throughout daily operations to ensure the chlorine is in the acceptable range. Testing will be conducted within the plant by the IPDC.

Analytical Method: Chlorine test kits will be used to verify the concentration of chlorine in the wash or spray water. Such test kits will be calibrated by comparing to known standards.

Chemistry Factor 2 - Refrigerated Foods - Salt Concentration of In-Process Control Points

Purpose: For certain food products, salt concentration contributes to the prevention of growth of certain microorganisms.

Sampling Plan: A minimum of 100 ml of liquid sample or 1/2 lb of solid sample should be collected for analysis. Solid samples or semifluid samples should be placed into a plastic bag and sealed. Plastic bottles should be used for liquid samples. Liquid samples may be analyzed without further sample preparation. Solid samples are to be prepared by passing through a food chopper with hole sizes of 1/8 inch or less (AOAC method 983.18). A food processor may be used instead of a food chopper (AOAC method 983.18, first supplement, 1990 to the 15th edition.)

Analytical Method: AOAC 935.47 (volumetric method) or AOAC 971.19 (QUANTAB method). Other methods such as a specific ion electrode may be used providing the equipment is calibrated for accuracy for the particular matrix being measured and the reproducibility is within ±10%.

Chemistry Factor 3 - Refrigerated Foods - pH

Purpose: The acidity of certain foods is adjusted to specific pH ranges to protect against the growth of certain microorganisms.

Sampling Plan: Samples should be prepared as in Factor 2 (Salt) above. The pH of liquid samples will be determined without additional sample preparation. Solid samples will be read directly (if equipment allows for surface readings) or further prepared by adding distilled water to a previously ground sample, and making a slurry before the pH determination is made. A slurry of solid samples will be made by mixing equal amounts by weight of distilled water and product.

Analytical Method: The pH will be determined according to Chemistry Laboratory Guidebook Method 3.02 and pH meter manufacturers guidelines. The meter should be calibrated prior to each use.

Chemistry Factor 4 - Refrigerated Foods - Unauthorized Preservatives in Finished Product

Purpose: Attempts are sometimes made to use certain unauthorized preservatives in fresh product to preserve the color of fresh meat. This practice is considered deceptive and a health hazard since the consumer is deprived of one of the important criteria used in judging the freshness of product.

Sampling Plan: Samples are to be prepared by passing through a food chopper with hole sizes of 1/8 inch or less (AOAC method 983.18). A food processor may be used instead of a food chopper (AOAC method 983.18, first supplement, 1990 to the 15th edition).

Analytical Method: Sulfites are detected by AOAC method 961.09 and 962.16 or 980.17. Ascorbic acid is detected by FSIS Chemistry Guidebook methods 6.004.

Physical

Physical Factor 1 - Refrigerated Foods - Organoleptic Wholesomeness

Purpose: Organoleptic signs of spoilage or contamination are indications of unacceptable product that may present health and safety risks.

Sampling Plan: Observations and verification tests of plant control at designated control points or CCP's will be collected by in-plant Agency personnel.

Analytical Method: Plant control of organoleptic wholesomeness will be assessed through observation of plant monitoring activity, plant records and plant reaction to deviations from established policy. Agency will conduct verification testing.

Units will be sampled and evaluated for off-odors and visual signs of foreign particle contamination or spoilage. Units will also receive tactile evaluation for temperature abuse, presence of slime, foreign bodies or other health and safety defects.

Physical Factor 2 - Refrigerated Foods - Temperature

Purpose: Product temperature is significant to the proliferation of microorganisms. By maintaining proper temperatures, undesirable microbial growth can be minimized.

Sampling Plan: See Physical Factor 1.

Analytical Method: Plant controls of product temperature will be assessed through observation of plant monitoring activities, plant records, and plant reactions to process deviations. In-plant Agency personnel will conduct verification tests.

Product and chamber temperatures will be measured. The temperature measuring device will be calibrated to an accuracy of within 1 degree F.

Physical Factor 3 - Refrigerated Foods - Restricted Ingredient Control

Purpose: Regulations limit the amounts of some restricted ingredients or food additives that may be added to products. Excessive amounts of some ingredients can cause health concerns.

Sampling Plan: See Physical Factor 1.

Analytical Method: Plant control of restricted ingredients will be assessed through observation of plant monitoring activities, plant records, and plant reactions to product deviations. In-plant Agency personnel will conduct verification tests.

For example, use of nitrites in cured sausage products will be monitored. Nitrites may be secondary barriers to microbial growth.

Physical Factor 4 - Refrigerated Foods - Time

Purpose: The length of time that a product is held in refrigerated storage or at room temperature is significant to the proliferation of microorganisms. It is important that raw meat storage at temperatures above 40 degrees F, and refrigerated unfrozen storage time be controlled to minimize microbial growth.

Sampling Plan: See Physical Factor 1.

Analytical Method: Plant control of time will be assessed through observation of plant monitoring activities, plant records, and plant reactions to process deviations. The Agency will conduct verification testing.

Observations shall include refrigerated raw meat storage time, raw meat holding time at above 40 degrees F, prior to heat processing, and frozen raw meat holding time after thawing until heat processing.

Physical Factor 5 - Refrigerated Foods - Sanitation—Employee Practices

Purpose: To prevent contamination of cooked product, specific employee sanitary product handling practices must be followed.

Sampling Plan: See Physical Factor 1.

Analytical Method: Plant control of employee sanitation practices will be assessed through observation of plant monitoring activities, plant records and plant reactions to process deviations. Agency will conduct verification testing.

Observations shall include whether all employees wash their hands whenever they enter a fully-cooked product area, or before handling unpackaged, cooked product; washing and sanitizing are as frequent as necessary during operations to avoid contamination of cooked product; sanitizer is germicidally equivalent to 50 ppm chlorine.

Employee outer-wear garments will be observed for identification or use in a fully-cooked area. Garments must be changed a minimum of once a day. These garments should be hung in a designated location before the employee leaves the area.

Physical Factor 6 - Refrigerated Foods - Heat Treatment/ Internal Temperature of Product

Purpose: Heat is often used to increase shelf life and decrease the number of microorganisms in food products. If heat treatment is inadequate, microorganisms may survive in the product, and cause foodborne illness.

Sampling Plan: See Physical Factor 1.
Analytical Method: Where applicable, the Agency will randomly select a portion of plant heat treatment records and review to determine the following information about the plant practices listed below: Determine whether and how plant monitors this information, if it is monitored at plant's established frequency, if plant records and evaluates results, and how plant reacts to deviations in its scheduled practices.

Examples of plant records and procedures that will be evaluated are the following:

- Records for thermal processing to determine if plant has specifications for time and temperature of heat treatment applied to product.

- Performance of calibration for thermometers, thermocouples, and wet/dry bulb thermometers.

- Humidity/steam specifications for heating unit settings, if applicable.

Physical Factor 7 - Refrigerated Foods - Separation of Cooked and Raw/Finished and Raw Product

Purpose: Raw and cooked or finished products must be separated throughout all phases of production to prevent cross-contamination. Cross-contamination can result in microorganisms being transferred to ready-to-eat products.

Sampling Plan: See Physical Factor 1.

Analytical Method: Agency will select written procedures and controls on cross-contamination, and determine whether and how plant monitors cooked and raw product separation, if it is monitored at plant's established frequency, if plant records and evaluates results, and how plant reacts to deviations from its established practices.

Examples of plant records and procedures that will be evaluated are the following:

- Control of cooked and raw product during cooling.

- Control of raw and finished product during product assembly.

Physical Factor 8 - Refrigerated Foods - Cooling Treatment

Purpose: After heating or cooking, product must be cooled to a specified temperature in an appropriate amount of time to render product safe.

Sampling Plan: See Physical Factor 1.

Analytical Method: Where appropriate, Agency will perform procedures and records examination to determine if plant controls are in place. Assessment will be made of plant monitoring activity, plant records, if and how plant evaluates monitoring results, and how plant reacts to deviations in its scheduled cooling practices.

For example, Agency personnel will monitor plant personnel calibrating temperature measurement devices, or in-plant recordings of time and temperature of cooling process delivered to product, to determine if the internal temperature reached by product is acceptable.

Physical Factor 9 - Refrigerated Foods - Environmental Control

Purpose: For plants where environmental control (e.g., positive pressure, microbial filtration of air, clean rooms) is used to enhance product shelf life and safety, it is important to monitor controls which exist in the plant.

Sampling Plan: See Physical Factor 1.

Analytical Method: Where applicable, throughout the process, plant control of the environment for special practices will be assessed. Agency personnel will observe the plant's environmental control records, and determine how the plant monitors this information and how the plant reacts to deviations in its scheduled practices.

Examples of plant records and procedures that will be evaluated are the following:

- Plant procedures for changing special air filters used for air supply.

- Plant monitoring of positive air pressure in processing areas of plant.

- Plant maintenance of positive air pressure in processing areas of plant.

- Plant maintenance of correct room temperature during product assembly.

- Plant maintenance of clean room procedures.

Physical Factor 10 - Refrigerated Foods - Package Integrity

Purpose: To determine plant control of package integrity, including package closures and seals, and gases filled into package headspace. Many products depend on the security of the seal or special types of gases filled into the package to deter microorganism proliferation.

Sampling Plan: See Physical Factor 1.

Analytical Method: Where applicable, plant control of package integrity will be assessed by observing a selected portion of the plant's package integrity control records. Determinations of how the plant monitors package integrity at the established frequency, how the plant records and evaluated results, and how the plant reacts to deviations in its scheduled practices.

Examples of plant records and procedures that will be evaluated are the following:

- Plant tests on durability of package seal, such as burst testing.
- Plant monitoring of gas composition going into packages.
- Plant maintenance of gas injection equipment.

Physical Factor 11 - Refrigerated Foods - Finished Product Identity/Date Coding of Product

Purpose: As products age, bacteria present in the package can multiply. If bacteria are of the pathogenic variety, food product can be rendered unsafe to eat. If date codes are used, and if product is identified, food producer knows when product is best removed from the retail market.

Sampling Plan: See Physical Factor 1.

Analytical Method: Where applicable, plant control of handling statement labeling, date coding, lot codes, expiration dates and shipping records, will be assessed by observing a selected portion of the plant's labeling and shipping control records. A determination of how the plant monitors appropriateness of codes, label statements, and shipping records, how the plant monitors established frequency, how plant records and evaluates results, and how plant reacts to deviations in its scheduled practices. Examples of plant records and procedures that will be evaluated are the following:

- Plant records of expiration dates of products and lot codes applied.
- Plant records of lots shipped, with expiration dates.
- Plant procedures to notify retailers that product has expired and must be removed from sale. Includes tracking of dated product.
- Product recall procedures.

Physical Factor 12 - Refrigerated Foods - Foreign Material Control

Purpose: Foreign objects in food can create a hazard to the consumer.

Sampling Plan: See Physical Factor 1.

Analytical Method: Plant control of foreign material entry into product will be assessed by observing a selected portion of plant foreign material monitoring activity. This includes: 1.) how plant monitors for entry of foreign materials into products, 2.) how records are kept, 3.) how the plant monitors for contamination at its established frequency, and 4.) how the plant reacts when deviations from established procedures and policy occur. Assessment will include Agency verification testing of plant procedures.

Examples of plant records and procedures that will be evaluated include: periodic emptying of metal detection devices, upkeep of light bulb shields, and condition of overhead storage areas.

Microbiology

Microbiology Factor 1 - Cooked Sausage - Aerobic Plate Count @ 35°C

Purpose: To compare profiles of total aerobic plate counts @ 35°C at selected locations and on finished product produced at volunteer plants prior to and after implementation of a HACCP plan.

Sampling Plan: Samples will be randomly selected at locations in processing areas prior to and after HACCP implementation. Finished product samples from a processing line will be selected prior to HACCP implementation and again after HACCP has been in operation.

Samples will be collected and shipped frozen to a FSIS Technical Support Laboratory according to FSIS Directive (Microbiological Sampling).

Analytical Method: The method shall be that described in Section 3 of the Microbiology Laboratory Guidebook (MLG, 1974), modified by the substitution of 3M Petri Film for APC enumeration (AOAC).

Microbiology Factor 2 - Cooked Sausage - Aerobic Plate Count @ 20°C

Purpose: To compare profiles of total aerobic plate counts @ 20°C at selected locations and on finished product produced at volunteer plants prior to and after implementation of a HACCP plan.

Sampling Plan: See Microbiology Factor 1.

Analytical Method: See Microbiology Factor 1.

Microbiology Factor 3 - Cooked Sausage - Coliforms

Purpose: To compare profiles of total coliforms at selected locations and on finished product produced at volunteer plants prior to and after implementation of a HACCP plan.

Sampling Plan: See Microbiology Factor 1.

Analytical Method: The method shall be that described in Section 3 of the MLG (1974), modified by the substitution of 3M Petri Film for the enumeration of coliforms (AOAC).

Microbiology Factor 4 - Cooked Sausage - *Escherichia Coli*

Purpose: To compare profiles of total *E. coli* at selected locations and on finished product produced at volunteer plants prior to and after implementation of a HACCP plan.

Sampling Plan: See Microbiology Factor 1.
Analytical Method: The method shall be that described in Section 3 of the MLG, modified by the substitution of 3M Petri Film for enumeration of *E. coli* (AOAC).

Microbiology Factor 5 - Cooked Sausage - *Staphylococcus Aureus*

Purpose: To compare profiles of total *S. aureus* on equipment and on finished product prior to and after implementation of a HACCP plan.

Sampling Plan: See Microbiology Factor 1.

Analytical Method: The method shall be the standard FSIS microbiological method contained in the MLG (1974).

Microbiology Factor 6 - Cooked Sausage - Gas Forming Anaerobes (GFA's)

Purpose: To compare profiles of total gas forming anaerobes at selected locations and on finished product produced at volunteer plants prior to and after implementation of a HACCP plan.

Sampling Plan: See Microbiology Factor 1.

Analytical Method: See Microbiology Factor 5.

Microbiology Factor 7 - Cooked Sausage - *Listeria* Species

Purpose: For evaluating the cleanliness of equipment during operations prior to and after implementation of a HACCP plan.

Sampling Plan: Swabs of equipment, as part of the preoperational sampling, and product that contacts non-food contact sources and equipment.

Samples will be collected and shipped frozen to a FSIS Technical Support Laboratory according to FSIS Directive (Microbiological Sampling).

Analytical Method: The method shall be the standard FSIS microbiological procedure described in Laboratory Communication 57, excluding speciation.

Microbiology Factor 8 - Cooked Sausage - Cooked Species

Purpose: To detect the presence of unlabeled animal species in cooked sausages which may cause allergic type reactions in susceptible individuals.

Sampling Plan: Finished product samples will be collected prior to and after HACCP implementation.

Samples will be collected and shipped frozen to a FSIS Technical Support Laboratory according to FSIS Directive (microbiological sampling).

Analytical Method: The method shall be the standard microbiological procedure described in Laboratory Communication 58.

Chemistry

Chemistry Factor 1 - Cooked Sausage - (Type II Protein Calculations)

Purpose: Cooked sausages may contain specific nonmeat proteins such as isolated soy protein, nonfat dry milk, either alone or in combination, up to an amount stated by regulations. Such nonmeat proteins (type II proteins) or mixtures of nonmeat proteins and seasonings are required to be labeled to show the percent protein. The protein contributed from type II proteins when added to a cooked sausage is subtracted from the total protein before added water calculations are made. Mislabeling could lead to the wrong protein or the wrong amount of protein added to the formulation. Since some people are allergic to certain proteins, it is important that such ingredients are accurately labeled.

Sampling Plan: Shipments will be selected at random for submission to a laboratory for label verification of % type II protein. A minimum of 1/2 lb sample will be placed in a plastic bag, sealed, and submitted for analysis. Supplier certifications will be verified and the % type II protein will be recorded. Corrective action will be indicated on samples where the analyses does not agree with the label declaration.

Analytical Method: The amount of type II protein is to be deducted from the total protein in calculations as stated in FSIS Directive 7140.2. This should be based on the label statement or as determined by analytical testing. The amount of type II protein is to be determined by either AOAC 928.08, 970.42, 977.14, or 981.10. The protein type will be verified by supplier certification.

Chemistry Factor 2 - Cooked Sausage - Nitrites/Nitrates

Purpose: Cooked sausage is allowed by regulation to contain a restricted amount of sodium or potassium nitrite and nitrate. The use of nitrites at a level not to exceed 200 ppm provides a margin of safety against the growth of certain microorganisms. Excessive amounts of these curing materials can present a health risk. These curing materials are usually received at an establishment and mixed with other components, such as salt. These mixtures must be accurately labeled to contain the correct amount of the curing agents, since these labeled concentrations are used in formulation calculations.

Sampling Plan: The analytical value for nitrites/nitrates for each shipment (lot) or in-plant formulated batch of curing material must be available. These analytical values may be obtained from either the supplier of the curing mixture or from testing conducted at the plant. A minimum of 6 ounces of curing mixture will be placed in a plastic bag and submitted for analysis. For cooked sausages, a 1-pound sample is placed in a plastic bag, sealed, and submitted for analysis. Samples will be prepared for analysis according to AOAC method 983.18. A food processor may be used instead of a food chopper (AOAC method 983.18, first supplement, 1990 to the 15th edition).

Analytical Method: Nitrites and nitrates in curing mixtures will be determined by FSIS Chemical Laboratory Guidebook methods 4.003, 4.004, or 4.005, as appropriate. Nitrites are determined in cooked sausages by AOAC methods 973.31.

Chemistry Factor 3 - Cooked Sausage - Salt Concentration

Purpose: The concentration of salt is a factor that affects the cooling rate of product after cooking and the proliferation of microorganisms.

Sampling Plan: Samples are to be prepared by passing through a food chopper with hole sizes of 1/8 inch or less (AOAC method 983.18). A food processor may be used instead of a food chopper (AOAC method 983.18, first supplement, 1990 to the 15th edition).

Analytical Method: The salt concentration is determined by AOAC 935.47 (volumetric method) or AOAC 971.19 (QUANTAB method).

Physical

Physical Factor 1 - Cooked Sausage - Organoleptic Wholesomeness

Purpose: Organoleptic signs of spoilage or contamination are indications of unacceptable product that may present health and safety concerns.

Sampling Plan: Observations and verification tests of plant control of organoleptic wholesomeness at designated CP's and CCP's will be carried out by the IPDC.

Analytical Method: Plant control of organoleptic wholesomeness will be assessed through observation of plant monitoring activity, plant records and plant reaction to deviations from established policy. The Agency will conduct verification testing at CP's, CCP's and finished product.

Units will be sampled and evaluated for off-odors and visual signs of foreign particle contamination or spoilage. Units will also be subjected to tactile evaluation for temperature abuse, presence of slime, foreign bodies or other health and safety defects.

Physical Factor 2 - Cooked Sausage - Temperature

Purpose: By maintaining proper temperatures, microorganism proliferation can be minimized.

Sampling Plan: See Physical Factor 1.

Analytical Method: Plant control of temperature will be assessed through observation of plant monitoring activities, plant records, and plant reactions to product deviations. In-plant Agency personnel will conduct verification tests.

Product and chamber temperatures will be measured. The temperature measuring device will be calibrated to accuracy within 1 degree F.

Physical Factor 3 - Cooked Sausage - Restricted Ingredient Control

Purpose: Excessive amounts of some ingredients can be cause for concern to susceptible or health-compromised persons.

Sampling Plan: See Physical Factor 1.

Analytical Method: Plant control of restricted ingredients will be assessed through observation of plant monitoring activities, plant records, and plant reactions to product deviations. Agency will conduct verification tests.

Use of nitrites in cured sausage products will be monitored. Nitrites may be secondary barriers to microbial growth.

Physical Factor 4 - Cooked Sausage - Time

Purpose: The length of time that a product is held in refrigerated storage or at room temperature is a parameter that controls the growth of microorganisms. It is important that raw meat storage at temperatures above 40 degrees F, and refrigerated unfrozen storage time be controlled to protect against microbial proliferation.

Sampling Plan: See Physical Factor 1.

Analytical Method: Plant control of time will be assessed through observation of plant monitoring activity, plant records, and plant reaction to deviations from established policy. The Agency will conduct verification testing.

Observations may include raw meat refrigerated storage time, raw meat holding time at above 40 degrees F before heat processing, and frozen raw meat holding time after thawing until heat processing.

Physical Factor 5 - Cooked Sausage - Sanitation—Employee Practices

Purpose: To prevent contamination of cooked product, employee personal hygiene and sanitary handling practices must be examined.

Sampling Plan: See Physical Factor 1.

Analytical Method: Plant control of employee sanitation practices will be assessed through observation of plant monitoring activity, plant records and plant reaction to deviations from established policy. The IPDC will conduct verification testing.

Observations may include employee hand-washing practices before handling unpackaged, cooked product; hand-washing and sanitizing practices during operations; and measurement of sanitizers.

Employee outer-wear garments will be observed for control of garments in processing areas, including the frequency of garment changing.

Physical Factor 6 - Cooked Sausage - Heat/Treatment/Internal Temperature of Product

Purpose: Heat is often used to increase shelf life and decrease the population of microorganisms in food products.

Sampling Plan: See Physical Factor 1.

Analytical Method: Where applicable, the IPDC will review a portion of plant heat treatment records and the following plant practices: how the plant monitors this information, how it is monitored at established frequency, how plant records and evaluates results, and how plant reacts to deviations in its scheduled practices.

Examples of plant records and procedures that will be evaluated are the following:

- Records for thermal processing to determine if plant has specifications for time and temperature of heat treatment applied to product.

- Performance of calibration for thermometers, thermocouples, and wet/dry bulb thermometers.

- Humidity/steam specifications for heating unit settings, if applicable.

Physical Factor 7 - Cooked Sausage - Separation of Cooked and Raw/Finished and Raw Product

Purpose: Cross-contamination of cooked and raw products can result in microorganisms being transferred to ready-to-eat products.

Sampling Plan: See Physical Factor 1.

Analytical Method: Agency will select written procedures and controls on cross-contamination and determine how the plant monitors cooked and raw product separation, how it is monitored at the established frequency, how the plant records and evaluates results, and how the plant reacts to deviations from its established practices. Examples of plant records and procedures that will be evaluated include:

- Cross-contamination program (raw and cooked or prepared products) is in place in all storage areas.

- Control of cooked and raw products during product preparation.

- Control of cooked and raw product during cooling.

- Control of raw and finished product occurs during product assembly.

Physical Factor 8 - Cooked Sausage - Cooling Treatment

Purpose: After heating or cooking, product must be properly cooled to be safe.

Sampling Plan: See Physical Factor 1.

Analytical Method: Where appropriate, the Agency will examine procedures and records to determine if plant controls are in place. Assessment will be made of plant monitoring activity, plant records, how the plant evaluates monitoring results, and how the plant reacts to deviations in its scheduled cooling practices. For example, the IPDC will monitor plant personnel calibrating temperature measurement devices, or in-plant recordings of the time and temperature of the cooling process for the product, to determine if the internal temperature reached by the product is acceptable.

Physical Factor 9 - Cooked Sausage - Environmental Control

Purpose: For plants where environmental control (e.g., positive pressure, microbial filtration of air, clean rooms) is used to enhance product shelf life and safety, it is important to monitor controls which exist in the plant.

Sampling Plan: See Physical Factor 1.

Analytical Method: Where applicable, throughout the process, plant control of the environment when special practices are used will be assessed. The IPDC will observe a selected portion of the plant's environmental control records, and determine how the plant monitors this information, how it is monitored at established frequency, how the plant records and evaluates results, and how the plant reacts to deviations in its scheduled practices.

Examples of plant records and procedures that will be evaluated are the following:

- Plant procedures for changing special air filters used for air supply.

- Plant monitoring of positive air pressure in processing areas of plant.

- Plant maintenance of positive air pressure in processing areas of plant.

- Plant maintenance of correct room temperature during product assembly.

- Plant maintenance of clean room procedures.

Physical Factor 10 - Cooked Sausage - Package Integrity

Purpose: Many products depend on the security of the seal or the special types of gases filled into the package to ensure product will remain safe in distribution and retail channels.

Sampling Plan: See Physical Factor 1.

Analytical Method: Where applicable, plant control of package integrity will be assessed by observing a selected portion of the plant's package integrity control records. Determinations will be made as to how the plant monitors package integrity, how it is monitored at the established frequency, how the plant records and evaluated results, and how the plant reacts to deviations in its scheduled practices.

Examples of plant records and procedures that will be evaluated are the following:

- Plant tests on durability of package seal, such as burst testing.

- Plant monitoring of gas composition going into packages. Involves plant analyzing gases injected into packages to verify gas equipment injection settings.

- Plant maintenance of gas injection equipment to assure it is operating properly.

Physical Factor 11 - Cooked Sausage - Finished Product Identity/Date Coding of Product

Purpose: As products age, bacteria present in the package can multiply. If bacteria are of the pathogenic variety, food product can be rendered unsafe to eat. If date codes are used, and if product is identified, food producer knows when product is best removed from the retail market.

Sampling Plan: See Physical Factor 1.

Analytical Method: Where applicable, plant control of handling statement labeling, date coding, lot codes, expiration dates and shipping records will be assessed by observing a selected portion of the plant's labeling and shipping control records. A determination will be made of how the plant monitors appropriateness of codes, label statements, and shipping records, how they are monitored at established frequency, how the plant records and evaluates results, and how the plant reacts to deviations in its scheduled practices.

Examples of plant records and procedures that will be evaluated are the following:

- Plant records of expiration dates of products and lot codes applied.

- Plant records of lots shipped, with their expiration dates.

- Plant procedures to notify retailers that product has expired. Includes tracking of dated product.

- Product recall procedures.

Physical Factor 12 - Cooked Sausage - Foreign Material Control

Purpose: Foreign objects in food can create a hazard to the consumer and plant control procedures can detect such contamination.

Sampling Plan: See Physical Factor 1.

Analytical Method: Plant control of foreign material entry into product will be assessed by observing a selected portion of plant foreign material monitoring activity. A determination will be made as to how the plant monitors for entry of foreign materials into products, how records are kept, how plant monitors for contamination at its established frequency, and how plant reacts when deviations from established procedures and policy occur. Assessment will include Agency verification testing of plant procedures.

Examples of plant records and procedures that will be evaluated include: periodic emptying of metal detection devices, upkeep of light bulb shields, and condition of overhead storage areas.

Microbiology

Microbiology Factor 1 - Poultry Slaughter - Aerobic Plate Count @ 35°C

Purpose: To compare profiles of total aerobic plate counts @ 35°C at selected locations and on raw final product produced at volunteer plants prior to and after implementation of a HACCP plan.

Sampling Plan: Samples will be selected at locations in processing areas prior to and after HACCP implementation.

Samples will be collected and shipped frozen to a FSIS Technical Support Laboratory according to FSIS Directive (Microbiological Sampling).

Analytical Method: The method shall be the procedure described in Section 3 of the MLG, modified by the substitution of 3M Petri Film for APC enumeration.

Microbiology Factor 2 - Poultry Slaughter - Coliforms

Purpose: To compare profiles of total coliforms at selected locations and on raw final product produced at volunteer plants prior to and after implementation of a HACCP plan.

Sampling Plan: See Microbiology Factor 1.

Method: The method shall be the procedure described in Section 3 of the MLG, modified by the substitution of 3M Petri Film for enumeration of coliforms.

Microbiology Factor 3 - Poultry Slaughter - *Escherichia Coli*

Purpose: To compare profiles of total *E. coli* at selected locations and on raw final product produced at volunteer plants prior to and after implementation of a HACCP plan.

Sampling Plan: See Microbiology Factor 1.

Analytical Method: The method shall be the procedure described in Section 3 of the MLG, modified by the substitution of 3M Petri Film for enumeration of *E. coli.*

Microbiology Factor 4 - Poultry Slaughter - *Staphylococcus Aureus*

Purpose: To compare profiles of total *S. aureus* at selected locations and on raw final product produced at volunteer plants prior to and after implementation of a HACCP plan.

Sampling Plan: See Microbiology Factor 1.

Analytical Method: The method shall be the standard FSIS microbiological method as described in the MLG.

Microbiology Factor 5 - Poultry Slaughter - Gas Forming Anareobes (GFA's)

Purpose: To compare profiles of total gas forming anaerobes at selected locations and on raw final product produced at volunteer plants prior to and after implementation of a HACCP plan.

Sampling Plan: See Microbiology Factor 1.

Analytical Method: See Microbiology Factor 4.

Microbiology Factor 6 - Poultry Slaughter - *Salmonella*

Purpose: To compare the occurrence and quantitative levels of salmonellae found on broiler carcasses collected at selected locations and on raw final product produced at volunteer plants before and after implementation of a HAACP plan.

Sampling Plan: See Microbiology Factor 1.

Analytical Method: The method shall be as described in *Food Technology* 1969, 23:80-85 and Section 4, MLG, as modified by the substitution of DMLIA plating media (*J. Food Protect.* 1988, *51*:391-396).

Chemistry

Chemistry Factor 1 - Poultry Slaughter - Chlorine In-Processing Water

Purpose: Chlorinated water is used to reduce the level of microorganisms in carcass chillers and in reprocessing procedures. Appropriate controls consist of calibration of metering devices, record keeping, and verification testing.

Sampling Plan: Samples will be taken throughout daily operations to ensure the chlorine is in an acceptable range.

Analytical Method: Chlorine test kits will be used to verify the concentration of chlorine in the wash or spray water. Such test kits will be calibrated by comparing to known standards.

Physical

Physical Factor 1 - Poultry Slaughter - Sanitation

Purpose: To determine the state of sanitation of slaughter facilities and equipment.

Sampling Plan: Observations will be made at a time(s) to be designated and may include before and/or after midshift

cleanup. Record all information on a form to be developed for this factor.

Analytical Method: Observe a sample of slaughter equipment, utensils and building structures for slaughter/processing debris.

Examples of debris that constitutes deficiencies may include the following, among others: dirt, grease, blood, tissues/fat, soap or cleaning compound residues, feathers, etc. Items in 12 categories will be evaluated. The categories will be as follows:

1. Evisceration shackles;
2. Chillers;
3. Pickers;
4. Product contact surfaces of tables;
5. Product contact surfaces of belts;
6. Walls, ceilings, floors;
7. Conveyor lines;
8. Overhead structures including pipes, lights, etc.;
9. Product contact surfaces of reprocessing station;
10. Product contact surfaces of salvage station;
11. Knives, gloves, aprons, and other product contact utensils; and
12. Automatic eviscerating equipment.

Information to be recorded will include the following: the date of inspection; the type of sanitation inspection, i.e., preoperational, operational, or midshift; a list of the items selected; a brief description of the deficiencies; classify each deficiency as critical, major, or minor, using the decision classification guide in FSIS Directive 8820.1, Corrective Action System; the number of deficiencies classified for each category, and the total number of defects in each classification category.

Physical Factor 2 - Poultry Slaughter - Product Handling

Purpose: To ensure that all condemned materials are prevented from being used as human food.

Sampling Plan: At locations within the plant to be designated, observe plant practices related to control and handling of condemned materials. The number of observations will be designated.

Analytical Method: Observe plant practices related to control and handling of all condemned materials. These observed practices will be scored as acceptable or unacceptable. Each incidence of condemnation of a carcass or a part will be scored. Acceptable practices will include the following: each condemned carcass and part is placed in appropriate, properly labeled condemn containers by plant employees; is properly denatured; and is maintained under control until disposal. Information to collect will include the following: the plant location where observations are made; the number of observations of acceptable practices, the number of observations of unacceptable practices, the total number of observations, and a brief narrative description of any unacceptable practices.

Physical Factor 3 - Poultry Slaughter - Contamination

Purpose: To determine the potential for fecal contamination and cross-contamination of product and equipment from carcasses leaking feces.

Sampling Plan: Observe all carcasses on the line for leaking/no leaking of feces for a length of time or number of carcasses to be designated.

Analytical Method: Observe and count all incidences of carcasses that are leaking feces and incidences of carcasses that are not leaking feces during processing. Examples of locations during processing where this factor may be significant would be: after drawing the viscera from the abdominal cavity; after the pickers and wash but before the rehang table; and at the rehang belt or table. Information to be collected will include the following: the location for the observations in the production line; the number of incidences of carcasses leaking feces; the number of carcasses not leaking feces; and the total number of incidences in each category at each location observations are made.

Physical Factor 4 - Poultry Slaughter - Sanitation

Purpose: To determine the level of sanitation of the automatic eviscerating machinery and the resulting potential for contamination and cross-contamination of product.

Sampling Plan: Record all incidences of accumulation/no accumulation of visible debris between carcasses on individual pieces of automatic eviscerating machinery for a length of time or number of carcasses to be designated.

Analytical Method: Observe and record the number of instances of accumulation/no accumulation of visible organic debris on the automatic eviscerating machinery between each carcass during production. When such equipment is properly adjusted, it should be self-cleaning or washed after each carcass evisceration and there should be no accumulation of visible debris. Debris may include the following, among others: viscera (full or partial sets), blood, feces, feathers, fat, tissue, etc.

Significant pieces of automatic eviscerating machinery that may be considered for data collection include the following, among others: the vent cutter, the opening cutter, and the eviscerator. Record the day of observations, the piece of automatic machinery observed, the number of instances of

accumulation/no accumulation, and a brief narrative description of any maintenance of the machinery or management actions related to processing control, such as adjustments to line speed, manual washing of equipment, etc., if observed.

Physical Factor 5 - Poultry Slaughter - Product Handling

Purpose: To determine the degree of accuracy with which inspection helpers respond to inspection instructions.

Sampling Plan: Observe all helper responses to inspection instructions for a length of time or number of instructions/carcasses to be designated.

Analytical Method: Observe and count the number of correct/incorrect inspection helper responses to instructions from inspectors. Inspector instructions to be included are the following: carcass dispositions and condemnations; trimming of pathology; and hanging back carcasses for veterinary disposition, online or offline salvage. The specific helper response, other than that for condemnation or hangback for veterinary disposition, will be based on the plant's marking system to identify carcasses for different types of salvaging procedures. All condemned carcasses must be immediately removed from the evisceration line and placed in properly labeled, controlled condemn containers. All carcasses hung back for veterinary disposition must be immediately removed from the evisceration line and hung back behind the inspector.

Other helper responses will depend on the plant's salvage systems used and marking system for carcasses to be salvaged. An example of such a plant designated marking system could include using red plastic tags on the shackle of all carcasses to be reprocessed, a green plastic tag for all carcasses to be salvaged for airsacculitis, etc. The system must provide clearly visible marking or identification for other plant employees. Inspection must have a written description of the system. Information to be collected will include the following: the date of information collection, the number of correct helper responses, the number of incorrect helper responses, the total number of responses in each category. Provide a brief narrative description of problems observed with communication and actions, types of incorrect actions, and relevant production information.

Physical Factor 6 - Poultry Slaughter - Product Handling

Purpose: To determine plant employee sanitary handling practices of salvaged and reprocessed products that are potential sources of contamination or cross-contamination of product.

Sampling Plan: Observe all salvage operations performed at off-line salvage stations, as appropriate to the individual plant. Each carcass or part that is salvaged at the station will be scored for sanitary handling practices.

Analytical Method: Observe and score as unacceptable or acceptable all plant employee handling practices of offline salvaged product that may result in cross-contamination, including at the hangback racks or lines associated with that salvage station. Acceptable practices are those that will not result in cross-contamination. Acceptable practices may include the following, among others: washing hands adequately when contaminated; cleaning equipment or salvage/reprocessing station following a salvage procedure; no piling up of contaminated parts on the salvage table; no cross-contamination of carcasses on hangback racks; no cross-contamination of parts on hangback racks; etc. Score each individual part or carcass salvage procedure as acceptable/unacceptable for sanitary handling practices.

Information to be collected will include the following: the date of production; the location, name, or function of each salvage area; the number of instances of acceptable sanitary handling practices; the number of instances of unacceptable sanitary handling practices; the total number of incidences for each category; and a brief narrative description of unacceptable sanitary handling practices observed.

Physical Factor 7 - Poultry Slaughter - Product Handling

Purpose: To ensure efficient product flow, time/temperature conformance, and minimize microbial proliferation.

Sampling Plan: Observe all salvage/reprocessed hangback rack or line carcasses for a length of time or number of carcasses to be designated.

Analytical Method: For carcasses that are to be salvaged or reprocessed, observe plant handling practices for a carcass hung on a rack or line before being salvaged/reprocessed, and score as acceptable or unacceptable. Information to be collected will include the following: the date of data collection; the type of salvage rack or line; the number of carcasses handled acceptably on racks or lines; and a narrative description of any visible deterioration of product such as drying out of skin during hangback for salvage, and information describing plant alternative procedures for salvaging such carcasses. Such alternative procedures may include condemnation or knife salvage.

Physical Factor 8 - Poultry Slaughter - Contamination

Purpose: To determine how effectively the manufacturing process controls visible contamination on carcasses going into the chillers.

Sampling Plan: Observe all carcasses online at locations to be designated before carcasses enter the chillers.

Analytical Method: Observe carcasses at locations to be designated before carcasses enter the chillers. Information to collect should include the following: the date of production; the location for data collection; the number of carcasses with no visible particles of fecal and/or ingesta contamination; the number of carcasses with visible particles of feces or ingesta ≥ 1/8 inch in size; the total number of carcasses observed; and a brief description of any relevant production information.

Physical Factor 9 - Poultry Slaughter - Contamination

Purpose: To determine the accuracy of plant salvage procedures in removing contamination from salvaged product and preventing cross-contamination.

Sampling Plan: A set of records to be designated will be reviewed.

Analytical Method: Review all records for observed instances of contamination by feces or ingesta on salvaged carcasses and parts. Data to be collected will include the following: the day of the record, the number of tests performed, the total number of instances from all tests performed on that day, and the total number of instances from the set of records examined.

Physical Factor 10 - Poultry Slaughter - Contamination

Purpose: To determine the accuracy of plant reprocessing procedures in removing all contamination from product and preventing cross-contamination.

Sampling Plan: A set of records to be designated will be selected.

Analytical Method: Review all records for observed instances of contamination by feces or ingesta on reprocessed carcasses and parts from reprocessed carcasses. Data to be collected will include the following: the day of the record, the number of log entries for the day, the total number of incidences from all tests performed for the day, and the total number of instances from the set of records examined.

Physical Factor 11 - Poultry Slaughter - Contamination

Purpose: To determine the accuracy of plant manufacturing process controls in removing all fecal contamination from online product before the product enters the chilling system and prevent cross-contamination of product in the chilling system.

Sampling Plan: A set of records to be designated will be selected.

Analytical Method: Review all records for observed instances of fecal contamination (line 8. Feces ≥ 1/8 inch) on all carcasses sampled at prechill. Data to be collected will include the following: the day of the record, the total number of instances from all tests performed on that day of production, and the total number of instances from the set of records examined.

Physical Factor 12 - Poultry Slaughter - Sanitation

Purpose: To evaluate the accuracy of plant sanitary controls in removing slaughter or processing debris from equipment, utensils and structures and in maintaining an adequate level of sanitation during production to prevent contamination of product.

Sampling Plan: A set of records to be designated will be selected.

Analytical Method: Review all FSIS-11,040-1 Sanitation Reports for sanitation deficiencies noted. Data to be collected will include the following: the date of the report; the type of sanitation inspection, i.e., preoperational, operational, or midshift; a list of deficiencies; a brief description of the defect; and a classification for each defect as critical, major, or minor, using the decision classification guide in FSIS Directive 8820.1 Corrective Action System; the number of defects classified for each category; and the total number of defects in each classification category for all records in the set.

IV. Qualitative Plant Data

Objectives

To understand HACCP implementation.

To explain the quantitative findings.

To identify the effects of HACCP on meat and poultry inspection operations.

Methodology

Qualitative factors have been identified that provide an overview in a processing or slaughter plant environment. These include objective data to assess 1.) the state of management's commitment, capabilities, and willingness to control the manufacturing process; and 2.) management's attitudes and commitment toward quality and regulatory compliance based on product impacts on consumer health and safety.

FSIS identified 11 significant categories:

1. General housekeeping,
2. Condition of facilities,
3. Employee hygiene,
4. Employee sanitary practices,
5. Employee attitudes toward inspection requirements,
6. Employee training,
7. Management supervisory attitudes,
8. Management response to problems,
9. Management strategies to prevent contamination hazards,
10. Product quality, and
11. Management programs and systems.

FSIS has identified specific examples of observation criteria for each of the major categories. Because not all significant issues were likely to be covered in every plant situation by the criteria identified, evaluators will be asked to give Narrative descriptions.

FSIS headquarters personnel will perform on-site total plant reviews both before and after the implementation of the test HACCP programs. At in-plant correlation meetings before the on-site reviews, FSIS personnel will be trained in the proper methods of the data collection to ensure consistency, accuracy, and comparability of findings.

FSIS personnel will be provided with sufficient time to review plant performance and complete the instrument. The applicable questions will be answered and issues addressed for each of the 11 qualitative factors or categories. Specific questions or issues are not intended to be construed as requirements for all plants or as all the possible relevant questions, but are rather intended to guide FSIS personnel to important "indicator" issues to be considered and data to be captured in the evaluation.

FSIS personnel will rate the findings for applicable questions or issues as high, medium, or low based on their discussions and agreements in the correlation sessions. A narrative description will be completed to provide additional supporting data to justify and explain FSIS' ratings on questions or issues and to summarize the overall judgment of the plant performance for that factor. Instances of excellence and weakness will be described in detail.

The evaluations will be performed in each plant at least twice by the same FSIS staff whenever possible. The identified plants will be evaluated during baseline data collection and following HACCP implementation. Repeated reviews would also minimize day-to-day plant operational variability that might unduly bias the data analysis.

V. FSIS Inspector and Plant Personnel Survey

Objective

To obtain information on the implementation experience with the HACCP model by interviewing FSIS inspectors and plant personnel involved in implementing HACCP in the volunteer plants.

Methodology

The interviews will be conducted with inspectors, inspectors-in-charge (IIC's), circuit supervisors (CS's), and plant officials. Whenever possible, FSIS personnel will conduct these interviews in person with the respondents. In the infrequent case when in-person interviews are not possible, mail and telephone may be used. Two questionnaires have been developed, one for FSIS personnel and one for plant officials. Initial contact with the respondent groups will be made through a letter from the Deputy Administrator for Inspection Operations to underscore the importance of participating in the survey and to highlight the topics to be covered.

VI. Literature Review

Objectives

To document the evolution of quality assurance in food inspection intended to ensure the safety of those products.

To demonstrate the consensus of existing scientific opinion relative to the application of HACCP systems in food production.

To identify the advantages and disadvantages in applying the HACCP system to the meat and poultry industry, with examples of applications to other industries.

Methodology

A literature search strategy is being developed to screen all relevant data bases for references to HACCP and related quality assurance concepts. Data bases to be searched include: AGRICOLA, Food Science and Technology Abstracts (FSTA), Biobusiness, FOODS ADLIBRA, BIOSIS Previews, CAB Abstracts, and AGRIS International. Materials will be reviewed to find out how quality assurance and HACCP principles have been applied to food production from the early part of the 20th century to the present. Additionally, writings of the National Academy of Sciences and proceedings of symposia on these subjects will be used in delineating the consensus of scientific opinion on the application of HACCP systems to food production. Current writers, thinkers, and researchers who have worked and published in these areas will be consulted.

The literature review will provide a historical overview of HACCP, including a discussion of the following topics: the inception of mandatory Federal meat inspection in 1906; microbiological control measures in the 1930's; the development of HACCP-like concepts through the decades; the application of HACCP to food processing in 1960's; use of HACCP today in the United States and internationally; and the endorsement of HACCP by professional groups.

The review will also cover the current uses of HACCP in the food industry and the Government (by such Agencies as FDA, NOAA, and FSIS). The application of HACCP to various food production systems will be explored, and the successes, difficulties, and lessons learned will be highlighted. Any insights from the use of HACCP or similar principles in industries other than food processing will be described.

Finally, the regulatory use of HACCP will be examined, along with case studies that show the advantages and disadvantages of the HACCP approach to inspection and how obstacles to its use may be overcome. Conclusions will be drawn regarding the use of HACCP in meat and poultry production and inspection, based on historical data culled from monographs, collective studies, periodicals, archival material, and consultation with experts.

APPENDIX A

United States Department of Agriculture
Food Safety and Inspection Service

HACCP Model Checklist

Instructions:

Following is a series of questions based on the brochure on HACCP developed by the National Advisory Committee on Microbiological Criteria for Foods. Each plant- and product-specific HACCP plan prepared is expected to provide answers to these questions to serve as a starting point in the safe production, handling, distribution, sale and preparation of food products. Reviewers of the plan will place a checkmark in the "YES" or "NO" block following each question provided the answer to the question is clearly addressed in the plan.

Certain questions require information which is specific to plants and products and, therefore, is not likely to be available when generic plans are developed. For this reason, a second checklist has been developed for use in reviewing generic HACCP plans. This checklist provides a block labeled "NOT FULLY APPLICABLE" following such questions.

United Stated Department of Agriculture
Food Safety Inspection Service

Checklist for Generic HACCP Model Plans

	YES	NO	NOT FULLY APPLICABLE
A. Description of product			
1. Does the plan submitted include:			
a. the producer/establishment, and the product name,	☐	☐	☐
b. the ingredients and raw materials used,	☐	☐	
c. the production process,	☐	☐	
d. the packaging used,	☐	☐	
e. the temperatures at which the product is intended to be held, distributed and sold, and	☐	☐	
f. the manner in which the product will be prepared for consumption?	☐	☐	
2. Has a flow diagram for the production of the food been submitted?	☐	☐	
3. Is the flow diagram specific for the facility producing the food?	☐	☐	☐
B. Hazard assessment			
1. Has a hazard assessment been performed on all ingredients prior to any processing step, including:			
a. hazard ranking, and,	☐	☐	
b. risk categorization?	☐	☐	

	YES	NO
2. Does this assessment of ingredients include:		
a. physical hazards,	☐	☐
b. chemical hazards, and,	☐	☐
c. microbiological hazards?	☐	☐
3. Has a hazard assessment been performed on final product, including:		
a. hazard ranking, and,	☐	☐
b. risk categorization?	☐	☐
4. Does this assessment of final product include:		
a. physical hazards,	☐	☐
b. chemical hazards, and	☐	☐
c. microbiological hazards?	☐	☐
5. Have all identified hazards been specifically listed?	☐	☐

C. Determination of critical control points

1. Has the control of all identified physical, chemical and microbiological hazards been assigned to identified critical control points (CCP's)?	☐	☐
2. Have these CCP's been entered on the flow diagram in numerical order?	☐	☐
3. Is the manner of control defined for each identified hazard?	☐	☐

	YES	NO	NOT FULLY APPLICABLE
D. Establishment of critical limits			
1. Have parameters necessary for control been identified for each CCP?	☐	☐	
2. Have critical limits been established for each parameter?	☐	☐	☐
E. Establishment of monitoring requirements			
1. Have monitoring procedures been provided to ensure that the parameters necessary for control at each CCP are maintained within the established critical limits?	☐	☐	☐
2. Are the monitoring procedures continuous or, where continuous is not possible, is the frequency of monitoring statistically based?	☐	☐	☐
3. Have procedures been developed for the systematic recording of monitoring data?	☐	☐	☐
4. Have the effectiveness of procedures for controlling chemical, physical and micro-biological hazards been established through testing?	☐	☐	
5. Have persons responsible for monitoring been identified?	☐	☐	☐
6. Have signatures of responsible individuals been required on monitoring data?	☐	☐	

	YES	NO	NOT FULLY APPLICABLE
F. Establishment of corrective actions			
1. Have specific corrective actions been developed for each CCP?	☐	☐	☐
2. Do the corrective actions address:			
a. re-establishment of control, and	☐	☐	☐
b. disposition of affected product?	☐	☐	☐
3. Have procedures been established to record these data?	☐	☐	
G. Establishment of effective record-keeping systems			
1. Have procedures been established to maintain the HACCP plan on file at the establishment?	☐	☐	☐
2. Have provisions been made to record information on ingredients when appropriate, such as:	☐	☐	
• supplier certification documenting compliance with processor's specifications,			
• processor audit records verifying supplier compliance,			
• storage temperature record for temperature-sensitive ingredients, and			
• storage time records of limited shelf-life ingredients?			

	YES	NO
3. Have provisions been made to record information relating to product safety when appropriate such as: • sufficient data and records to establish the efficacy of barriers in maintaining product safety, • sufficient data and records establishing the safe shelf of the product, and • documentation of the adequacy of the processing procedures from a knowledgeable process authority?	☐	☐
4. Have provisions been made to record information on processing when appropriate such as: • records from all monitored CCP's, and, • system records verifying the continued adequacy of the processes?	☐	☐
5. Have provisions been made to record information on packaging when appropriate such as: • records indicating compliance with specifications of packaging materials, and, • records indicating compliance with sealing specifications?	☐	☐
6. Have provisions been made to record information on storage and distribution when appropriate such as: • temperature records, and • records showing no product shipped after shelf-life date on temperature-sensitive products?	☐	☐

	YES	NO	NOT FULLY APPLICABLE
7. Have provisions been made to record modifications to the HACCP plan file indicating approved revisions and changes in ingredients, formulations, processing, packaging, and distribution control, as needed?	☐	☐	
H. Establishment of verification procedures			
1. Have procedures been included to verify that all hazards were identified in the HACCP plan when it was developed?	☐	☐	
2. Have procedures been included to verify that the HACCP system is in compliance with the HACCP plan?	☐	☐	
3. Has the frequency of verification inspection been established?	☐	☐	☐
4. Has provision been made for verification testing reports to include the following elements:			
a. Existence of an approved HACCP plan and designation of person(s) responsible for administering and updating the HACCP plan,	☐	☐	☐
b. all records and documents associated with CCP monitoring must be signed by the person monitoring and approved by a responsible official of the firm,	☐	☐	
c. direct monitoring data of the CCP while in operation,	☐	☐	
d. certification that monitoring equipment is properly calibrated and in working order,	☐	☐	
e. deviation procedures, and	☐	☐	
f. any sample analysis for attributes confirming that CCP's are under control to include physical, chemical, microbiological • or organoleptic methods?	☐	☐	

United States Department of Agriculture
Food Safety and Inspection Service

HACCP Model Checklist

Instructions:

Following is a series of questions based on the brochure on HACCP developed by the National Advisory Committee on Microbiological Criteria for Foods. Each plant- and product-specific HACCP plan prepared is expected to provide answers to these questions to serve as a starting point in the safe production, handling, distribution, sale and preparation of food products. Reviewers of the plan will place a checkmark in the "YES" or "NO" block following each question provided the answer to the question is clearly addressed in the plan.

Certain questions require information which is specific to plants and products and, therefore, is not likely to be available when generic plans are developed. For this reason, a second checklist has been developed for use in reviewing generic HACCP plans. This checklist provides a block labeled "NOT FULLY APPLICABLE" following such questions.

United Stated Department of Agriculture
Food Safety Inspection Service

Checklist for Plant- and Product-Specific HACCP Model Plans

	YES	NO
A. Description of product		
1. Does the plan submitted include:		
a. the producer/establishment, and the product name,	☐	☐
b. the ingredients and raw materials used,	☐	☐
c. the production process,	☐	☐
d. the packaging used,	☐	☐
e. the temperatures at which the product is intended to be held, distributed and sold, and	☐	☐
f. the manner in which the product will be prepared for consumption?	☐	☐
2. Has a flow diagram for the production of the food been submitted?	☐	☐
3. Is the flow diagram specific for the facility producing the food?	☐	☐
B. Hazard assessment		
1. Has a hazard assessment been performed on all ingredients prior to any processing step, including:		
a. hazard ranking, and,	☐	☐
b. risk categorization?	☐	☐

	YES	NO
2. Does this assessment of ingredients include:		
a. physical hazards,	☐	☐
b. chemical hazards, and,	☐	☐
c. microbiological hazards?	☐	☐
3. Has a hazard assessment been performed on final product, including:		
a. hazard ranking, and,	☐	☐
b. risk categorization?	☐	☐
4. Does this assessment of final product include:		
a. physical hazards,	☐	☐
b. chemical hazards, and	☐	☐
c. microbiological hazards?	☐	☐
5. Have all identified hazards been specifically listed?	☐	☐

C. Determination of critical control points

1. Has the control of all identified physical, chemical and microbiological hazards been assigned to identified critical control points (CCP's)?	☐	☐
2. Have these CCP's been entered on the flow diagram in numerical order?	☐	☐
3. Is the manner of control defined for each identified hazard?	☐	☐

	YES	NO
D. Establishment of critical limits		
1. Have parameters necessary for control been identified for each CCP?	☐	☐
2. Have critical limits been established for each parameter?	☐	☐
E. Establishment of monitoring requirements		
1. Have monitoring procedures been provided to ensure that the parameters necessary for control at each CCP are maintained within the established critical limits?	☐	☐
2. Are the monitoring procedures continuous or, where continuous is not possible, is the frequency of monitoring statistically based?	☐	☐
3. Have procedures been developed for the systematic recording of monitoring data?	☐	☐
4. Have the effectiveness of procedures for controlling chemical, physical and micro-biological hazards been established through testing?	☐	☐
5. Have persons responsible for monitoring been identified?	☐	☐
6. Have signatures of responsible individuals been required on monitoring data?	☐	☐

	YES	NO
F. Establishment of corrective actions		
1. Have specific corrective actions been developed for each CCP?	☐	☐
2. Do the corrective actions address:		
a. re-establishment of control, and	☐	☐
b. disposition of affected product?	☐	☐
3. Have procedures been established to record these data?	☐	☐
G. Establishment of effective record-keeping systems		
1. Have procedures been established to maintain the HACCP plan on file at the establishment?	☐	☐
2. Have provisions been made to record information on ingredients when appropriate, such as:	☐	☐
• supplier certification documenting compliance with processor's specifications,		
• processor audit records verifying supplier compliance,		
• storage temperature record for temperature-sensitive ingredients, and		
• storage time records of limited shelf-life ingredients?		

	YES	NO
3. Have provisions been made to record information relating to product safety when appropriate such as: • sufficient data and records to establish the efficacy of barriers in maintaining product safety, • sufficient data and records establishing the safe shelf of the product, and • documentation of the adequacy of the processing procedures from a knowledgeable process authority?	☐	☐
4. Have provisions been made to record information on processing when appropriate such as: • records from all monitored CCP's, and, • system records verifying the continued adequacy of the processes?	☐	☐
5. Have provisions been made to record information on packaging when appropriate such as: • records indicating compliance with specifications of packaging materials, and, • records indicating compliance with sealing specifications?	☐	☐
6. Have provisions been made to record information on storage and distribution when appropriate such as: • temperature records, and • records showing no product shipped after shelf-life date on temperature-sensitive products?	☐	☐

	YES	NO
7. Have provisions been made to record modifications to the HACCP plan file indicating approved revisions and changes in ingredients, formulations, processing, packaging, and distribution control, as needed?	☐	☐

H. Establishment of verification procedures

1. Have procedures been included to verify that all hazards were identified in the HACCP plan when it was developed?	☐	☐
2. Have procedures been included to verify that the HACCP system is in compliance with the HACCP plan?	☐	☐
3. Has the frequency of verification inspection been established?	☐	☐
4. Has provision been made for verification testing reports to include the following elements:		
a. Existence of an approved HACCP plan and designation of person(s) responsible for administering and updating the HACCP plan,	☐	☐
b. all records and documents associated with CCP monitoring must be signed by the person monitoring and approved by a responsible official of the firm,	☐	☐
c. direct monitoring data of the CCP while in operation,	☐	☐
d. certification that monitoring equipment is properly calibrated and in working order,	☐	☐
e. deviation procedures, and	☐	☐
f. any sample analysis for attributes confirming that CCP's are under control to include physical, chemical, microbiological or organoleptic methods?	☐	☐

APPENDIX B

United States Department of Agriculture
Food Safety and Inspection Service

Qualitative Evaluation of Volunteer HACCP Plants

Evaluation Identification

ESTABLISHMENT NUMBER: _____

OPERATION EVALUATED: ☐ Slaughter ☐ Processing

TYPE OF EVALUATION: ☐ Baseline Data ☐ HACCP Test Data

DATE OF EVALUATION: _____

NAME OF EVALUATOR: _____

TYPE OF PRODUCT: _____

Factor I — General Housekeeping

Purpose: Determine the general state of housekeeping and sanitation in the entire plant.

Focus Issues

Please observe and evaluate each issue described on the list provided below as indicators of overall plant performance for this factor. Check an appropriate block to indicate your judgment of whether **General Housekeeping** is HIGH, MEDIUM, or LOW for this issue. Please explain all LOW answers in the narrative block on the following page. Indications of HIGH performance also should be described in the narrative. Also note in the narrative block which of the focus issues are not applicable to this plant and any for which the evaluator cannot make a judgment.

	HIGH	*MEDIUM*	*LOW*
1. Trash containers. *[Consider: is there an adequate number of trash containers; are they located appropriately; are they adequately identified; are trash containers allowed to overflow; what condition are trash containers; etc.]*	☐	☐	☐
2. Storage of boxes, pallets, extra equipment, supplies, etc. *[Consider: the type, condition, and placement of storage racks for sanitation; are materials stacked appropriately; are storage areas cluttered, congested, and not easily cleanable; etc.]*	☐	☐	☐
3. Control of product that falls on the floor. *[Consider: what plant preventive measures, if any, are used to control floor product; what kind of actions are taken and when, and how does the plant handle, dispose of, and salvage product that falls on the floor; how often and what quantity of product falls on the floor; etc.]*	☐	☐	☐
4. Control of processing debris that falls on the floor ***(includes ice, viscera, inedible product, etc.).*** *[Consider: what plant preventive measures, if any, are used to control processing debris; what kind of actions are taken and when, how does the plant handle processing debris; how often and how much of such debris falls on the floor; does it constitute a sanitary nuisance; etc.]*	☐	☐	☐
5. Sanitation or cleanup staff. *[Consider: who does sanitation/cleanup; are sanitation staff and sanitation monitored by plant management/QC/QA; are sanitation equipment and chemicals adequate; are there delays in production because of problems with sanitation; who does sanitation at mid-shift; is midshift cleanup monitored by management/QA/QC; is operational sanitation adequate; etc.]*	☐	☐	☐

	HIGH	MEDIUM	LOW
6. Control of bad odors. *[Consider: drains, spoiled meat in and under equipment, offal room ventilation; evisceration ventilation; etc.]*	☐	☐	☐
7. Microbiological control monitoring program for effectiveness of sanitation program. *[Consider: does the plant use microbiological swabbing of equipment to verify QC/QA; are communication and correlation with sanitation staff adequate to resolve problems with sanitation; etc.]*	☐	☐	☐
8. Plant design and layout. *[Consider: is the plant equipment placement and location for sanitary facilities, salvage stations storage areas, work stations for employees, etc., adequate for ease of accessibility to equipment and product, safe and efficient product flow, safety for workers; are there layout or space problems that interfere with the above factors and may contribute to a potential for contamination of product; etc.]*	☐	☐	☐

Narrative

Please use the remaining space to record your impressions and comments about general housekeeping in this plant. Include an overall summary appraisal of the plant's operations related to this factor. Note any focus questions that did not apply in this plant. Describe instances of observed excellence as well as shortcomings. Continue on additional sheets if necessary.

Factor II — Condition of Facilities

Purpose: Assess the commitment of plant management to provide and maintain adequate facilities in a safe, clean condition; appraise facilities' impact on process control, plant employees' ability to produce safe, healthy products, and inspector's ability to inspect.

Focus Issues

Please observe and evaluate each issue described on the list provided below as indicators of overall plant performance for this factor. Check an appropriate block to indicate your judgment of whether **Condition of Facilities** is HIGH, MEDIUM, or LOW for this issue. Please explain all LOW answers in the narrative block on the following page. Indications of HIGH performance should also be described in the narrative. Also note in the narrative block which of the focus issues are not applicable to this plant and any for which the evaluator cannot make a judgment.

	HIGH	*MEDIUM*	*LOW*
1. Maintenance of outside premises. *[Consider: type and condition of the ground surfaces; potholes; condition of any glass windows; presence and condition of screens on doors and windows; condition of outside wall surfaces; cracks/holes in walls; litter and debris; condition of grassy areas or landscaping; weeds, tall grass; etc.]*	☐	☐	☐
2. Maintenance of loading docks. *[Consider: type and sanitary condition of floors; presence of holes, debris or litter; state of cleanliness; presence of mud, dirt, grease, or other contamination; presence of standing water; type and condition of doors; use of air or strip curtains; adequate control of opening/closing of doors; etc.]*	☐	☐	☐
3. Maintenance of shipping/receiving areas. *[Consider: type and sanitary condition of floors and doors; presence of holes; closing of doors; use of air or strip curtains; debris or litter; adequate drainage of surfaces; are there adequate and sanitary conditions and facilities for storage and handling of materials received or to be shipped; etc.]*	☐	☐	☐
4. Maintenance of coolers and freezers. *[Consider: type and sanitary condition of floors, walls, ceiling surfaces; are permanent racks used; what type and sanitary condition are the racks; is drainage adequate; is there an accumulation of debris; is product maintained in a sanitary condition; is there ice/frost buildup; is the space adequate or cluttered; is cleaning regularly scheduled; is cleaning adequate; etc.]*	☐	☐	☐

	HIGH	MEDIUM	LOW
5. Maintenance of product processing and handling areas. *[Consider: type and sanitary condition of floor, walls, and ceiling surfaces; are there holes, gouges, painted surfaces, rust, condensation, or drips; is debris or litter present; is there adequate space for storage of equipment and supplies; is the storage layout accessible for sanitation; is there adequate drainage; what is the type and sanitary condition of product contact and other work surfaces; is there adequate space for suitable work surfaces; are sanitary work surfaces available such as tables, or are unsuitable work surfaces used such as conveyors, pallets, etc.; state of cleanliness; etc.]*	☐	☐	☐
6. Maintenance of product-contact. *[Consider: type and sanitary condition of surfaces; is repaired equipment in sanitary condition; welds, holes, rusting, etc.; is paint flaking or in need of repair; are the design and layout of equipment adequate for accessibility for cleaning; etc.]*	☐	☐	☐
7. Employee welfare facilities. *[Consider: are there enough welfare facilities for the number of employees of each sex; are welfare facilities readily accessible for employees; are they maintained adequately in sanitary condition; what is their state of cleanliness; are lighting and ventilation adequate; is there litter/debris present; etc.]*	☐	☐	☐
8. Preventive maintenance program. *[Consider: is there a written program for plant preventive maintenance; is there regularly scheduled service for facilities/equipment; how is emergency maintenance handled to protect product and maintain a sanitary environment; is long- and/or short-term planning being done for maintenance requirements; etc.]*	☐	☐	☐
9. Plant improvement plan. *[Consider: are improvements generally management- or inspector-driven; who sets time frames and are they realistic and met; are inspectors informed and involved in planning for changes/additions; etc.]*	☐	☐	☐

Narrative

Please use the remaining space to record your impressions and comments about the facilities in this plant. Include an overall summary appraisal of the plant's operations related to this factor. Note any focus questions that did not apply in this plant. Describe instances of observed excellence as well as shortcomings. Continue on additional sheets if necessary.

Factor III — Plant Employee Personal Hygiene

Purpose: Determine the level of personal hygiene practiced by company employees. Includes management, Quality Control specialists, line workers, maintenance workers, and cleanup employees.

Focus Issues

Please observe and evaluate each issue described on the list provided below as indicators of overall plant performance for this factor. Check an appropriate block to indicate your judgment of whether **Plant Employee Personal Hygiene** is HIGH, MEDIUM, or LOW for this issue. Please explain all LOW answers in the narrative block on the following page. Indications of HIGH performance should also be described in the narrative. Also note in the narrative block which of the focus issues are not applicable to this plant and any for which the evaluator cannot make a judgment.

	HIGH	*MEDIUM*	*LOW*
1. Employee handwashing practices. *[Consider: how complete are employee handwashing practices; how effectively do employees use soap, sanitizers, hand creams; do employees follow proper handwashing techniques including scrubbing, rinsing, drying; do employees always wash their hands properly to prevent product contamination, such as after sneezing/coughing, using the bathroom, handling contaminated equipment or product; etc.]*	☐	☐	☐
2. Employee clothing. *[Consider: are street clothes covered adequately; is plant clothing clean, well-mended, changed as appropriate when contaminated or before entering a cleaner area; what protective clothing is worn by maintenance workers and visitors; does the plant provide suitable, clean protective clothing for employees; etc.]*	☐	☐	☐
3. Other employee protective coverings. *[Consider: types of hair coverings used; are beard nets used/required; is hair adequately restrained; is employee footwear sanitary; are footwear and hair coverings worn by maintenance workers and visitors sanitary; etc.]*	☐	☐	☐
4. Company hygiene policies. *[Consider: does the plant have written hygiene policies; what is the plant policy on hair nets, beard nets, length of hair, use of sanitizing hand dips or foot baths; are hygiene policies posted on signs in appropriate locations; does management or QA/QC monitor employee sanitary hygiene practices; what are plant policies for sick employees or ones with infected wounds or sores; does the plant have any programs to prevent employee carpal tunnel syndrome; is there a health professional, such as a nurse, on duty for plant employees; etc.]*	☐	☐	☐

	HIGH	MEDIUM	LOW
5. Visibility of company hygiene policies. *[Consider: written rules, training, monitoring plan, enforcement, posters; are employees' actions related to hygiene inspection, management, or self-motivated; etc.]*	☐	☐	☐
6. Scope of company hygiene policies. *[Consider: topics such as hair nets, beard nets, length of hair, sick employees, employees with infected wounds or sores, use of sanitizing hand dips or foot baths, etc.]*	☐	☐	☐

Narrative

Please use the remaining space to record your impressions and comments about employee hygiene practices in this plant. Include an overall summary appraisal of the plant's operations related to this factor. Note any focus questions that did not apply in this plant. Describe instances of observed excellence as well as shortcomings. Continue on additional sheets if necessary.

Factor IV — Plant Employee Sanitary Practices

Purpose: Determine the level of employee sanitary practices while handling product. Scope includes management, Quality Control specialists, line workers, maintenance workers, and cleanup employees.

Focus Issues

Please observe and evaluate each issue described on the list provided below as indicators of overall plant performance for this factor. Check an appropriate block to indicate your judgment of whether **Plant Employee Sanitary Practices** is HIGH, MEDIUM, or LOW for this issue. Please explain all LOW answers in the narrative block on the following page. Indications of HIGH performance should also be described in the narrative. Also note in the narrative block which of the focus issues are not applicable to this plant and any for which the evaluator cannot make a judgment.

	HIGH	*MEDIUM*	*LOW*
1. Employee practices to prevent cross-contamination. *[Consider: what are employee product handling practices to separate raw from cooked products and how effective are those practices; does the plant use an identification system for employees working with certain products/areas/processes, such as color-coded uniforms; does the plant provide and require use of sanitizing or disinfectant hand dips and/or foot baths; etc.]*	☐	☐	☐
2. Sanitary handling practices of management and QC employees. *[Consider: what are supervisor's sanitary product handling practices; what precautions are taken by supervisors when handling product; what QC/QA employee sanitary practices and precautions are taken when handling/sampling product; are these practices adequate to prevent contamination; etc.]*	☐	☐	☐
3. Employee foot and machinery traffic in the plant. *[Consider: are there areas in the plant where employee traffic is limited; does the plant prevent excessive employee traffic that may potentially contaminate product; are employees supervised and restricted in movement through the plant; are sanitizing foot baths or hand dips present, properly filled, and used regularly by employees; are different gloves or clothing used by employees in cooked product areas or employees changing to different work areas; is product flow after cooking adequate to prevent cross-contamination; is automated product handling equipment, such as fork lifts, a potential contamination problem for product; etc.]*	☐	☐	☐

	HIGH	MEDIUM	LOW
4. Sanitary precautions used by maintenance employees. *[Consider: is preventive maintenance scheduled; how are emergency breakdowns repaired so product does not become contaminated; who monitors maintenance employees working on emergency breakdowns and who is responsible for assuring that sanitation is adequate prior to use of repaired equipment; is that oversight adequate and are practices effective; etc.]*	☐	☐	☐
5. Sanitary handling of contaminated product. *[Consider: are there contamination detection devices in use in the plant, such as metal detectors; are there specified product rework areas available and properly staffed and equipped for salvage; are there written handling and salvage procedures for contaminated product; how is contaminated product safely separated from uncontaminated product and equipment; are contaminated utensils such as knives adequately washed/sanitized between incidents or carcasses; how is salvage monitored; who determines compliance with salvage; are inspectors notified promptly of contamination and salvage incidents; etc.]*	☐	☐	☐
6. Sanitary handling of offal. *[Consider: are there written procedures for handling offal, edible and inedible; how is inedible offal separated to prevent contamination of edible product and equipment; are sanitary controls adequate; are employees and equipment in the offal department identifiable; are employees and equipment in the offal department restricted in their movements and use to prevent crose-contamination in other departments; who does sanitary handling of offal and how is it monitored; etc.]*	☐	☐	☐
7. Chilling and freezing procedures and handling. *[Consider: what are the sanitary conditions where carcasses are stored; are condensation, rain, rust, frost, ice, etc. present; sanitary conditions where cuts of meat and processed products are stored; is there potential for contamination of product during chilling/freezing; do workers use special, clean protective clothing for working in freezers or coolers; etc.]*	☐	☐	☐
8. Sanitary storage of product contact items. *[Consider: the sanitary conditions where spices, food ingredients, boxes, labels, etc., are stored; are boxes stored in aisles in plant; is there debris or litter present; are there signs of rodent/insect infestation in storage areas; are chemicals for cleaning and pesticides stored adequately and separately from product contact items; are wood pallets used as storage racks; etc.]*	☐	☐	☐

Narrative

Please use the remaining space to record your impressions and comments about general housekeeping in this plant. Include an overall summary appraisal of the plant's operations related to this factor. Note any focus questions that did not apply in this plant. Describe instances of observed excellence as well as shortcomings. Continue on additional sheets if necessary.

Factor V — Plant Employee Attitudes about Inspection

Purpose: Identify attitudes of company employees at all levels towards inspectors and conformance with inspection requirements. Include management, Quality Control specialists, line workers, maintenance workers, and cleanup employees.

Focus Issues

Please observe and evaluate each issue described on the list provided below as indicators of overall plant performance for this factor. Check an appropriate block to indicate your judgment of whether **Plant Employee Attitudes about Inspection** is HIGH, MEDIUM, or LOW for this issue. Please explain all LOW answers in the narrative block on the following page. Indications of HIGH performance should also be described in the narrative. Also note in the narrative block which of the focus issues are not applicable to this plant and any for which the evaluator cannot make a judgment.

	HIGH	*MEDIUM*	*LOW*
1. Cooperation with inspection by supervisors, managers, and workers.			
• are plant records readily available to inspectors.	☐	☐	☐
• do managers and supervisors respond and cooperate with inspector concerns or requests.	☐	☐	☐
• does management discuss projects during planning with inspectors and listen to inspector concerns for product safety.	☐	☐	☐
• does management keep inspectors informed of plans for changes in programs, production, or facilities.	☐	☐	☐
• does management demonstrate a visible commitment to safe and sanitary food production.	☐	☐	☐
• does management work with the FSIS management structure for approval of programs, information, and decisions.	☐	☐	☐
2. Maintenance of inspection office by the plant. *[Consider: is the inspection office maintained in a sanitary condition; are facilities and equipment provided by plant management for inspector's use adequate; is the inspection office space adequate and accessible to slaughter/processing areas in plant; are there separate rest room facilities and/or separate locker rooms provided for male and female inspectors; etc.]*	☐	☐	☐

Narrative

Please use the remaining space to record your impressions and comments about employee attitudes toward inspectors and inspection requirements in this plant. Include an overall summary appraisal of the plant's operations related to this factor. Note any focus questions that did not apply in this plant. Describe instances of observed excellence as well as shortcomings. Continue on additional sheets if necessary.

Factor VI — Plant Employee Training

Purpose: Determine management's commitment to provide all employees with adequate training in order to produce safe, healthy products. Include management, Quality Control specialists, line workers, maintenance workers, and cleanup employees.

Focus Issues

Please observe and evaluate each issue described on the list provided below as indicators of overall plant performance for this factor. Check an appropriate block to indicate your judgment of whether **Plant Employee Training** is HIGH, MEDIUM, or LOW for this issue. Please explain all LOW answers in the narrative block on the following page. Indications of HIGH performance should also be described in the narrative. Also note in the narrative block which of the focus issues are not applicable to this plant and any for which the evaluator cannot make a judgment.

	HIGH	*MEDIUM*	*LOW*
1. Employee training programs provided for:			
• sanitary personal hygiene.	☐	☐	☐
• sanitary product handling practices.	☐	☐	☐
• special training for individual responsibilities.	☐	☐	☐
2. Other management actions or programs provided for:			
• employee in-plant refresher training.	☐	☐	☐
• plant monitoring or testing of employees on materials presented in training.	☐	☐	☐
• Total Quality Management or other employee involvement quality improvement programs, i.e. quality circles.	☐	☐	☐
• outside training for employees, i.e. Better Process Control School, National Food Processors Institute workshops, or FSIS training.	☐	☐	☐
• encouragement of employees to become certified as food handlers.	☐	☐	☐
• continuing education assistance for employees.	☐	☐	☐
• multi-lingual training and supervision for employees.	☐	☐	☐

Narrative

Please use the remaining space to record your impressions and comments about management attitudes toward employee training in this plant. Include an overall summary appraisal of the plant's operations related to this factor. Note any focus questions that did not apply in this plant. Describe instances of exemplary attitudes as well as shortcomings. Continue on additional sheets if necessary.

Factor VII – Plant Management Attitudes Toward Employee Supervision

Purpose: Identify management attitudes towards supervision and the methods used to achieve employee performance of work functions.

Focus Issues

Please observe and evaluate each issue described on the list provided below as indicators of overall plant performance for this factor. Check an appropriate block to indicate your judgment of whether **Plant Management Attitudes Toward Employee Supervision** is HIGH, MEDIUM, or LOW for this issue. Please explain all LOW answers in the narrative block on the following page. Indications of HIGH performance should also be described in the narrative. Also note in the narrative block which of the focus issues are not applicable to this plant and any for which the evaluator cannot make a judgment.

	HIGH	*MEDIUM*	*LOW*
1. Management programs:			
• to encourage and use employee suggestions to improve production.	☐	☐	☐
• program to use Total Quality Management, or other employee involvement quality improvement programs, training, etc.	☐	☐	☐
• use of TQM principles by supervisors.	☐	☐	☐
• training supervisors in communication skills or in flexible, participatory management and problem-solving, or other progressive management techniques.	☐	☐	☐
• display multi-lingual posters or signs for employee instructions and information, such as on safety and sanitation.	☐	☐	☐
2. Staffing:			
• management provides adequate staffing of line jobs appropriate for the level of production.	☐	☐	☐
• management actively tries to retain personnel	☐	☐	☐
• plant has a great turnover in personnel.	☐	☐	☐
• management has extra staff available for problems when they occur.	☐	☐	☐

Narrative

Please use the remaining space to record your impressions and comments about management attitudes toward employees in this plant. Include an overall summary appraisal of the plant's operations related to this factor. Note any focus questions that did not apply in this plant. Describe instances of exemplary attitudes as well as shortcomings. Continue on additional sheets if necessary.

Factor VIII — Plant Management Response to Problems

Purpose: Determine management's methods for dealing with loss of process control, emergencies, or other difficult situations. Examples may include carcasses on floor, excessive contamination or pathology, power outage, natural disaster, etc.

Focus Issues

Please observe and evaluate each issue described on the list provided below as indicators of overall plant performance for this factor. Check an appropriate block to indicate your judgment of whether **Plant Management Response to Problems** is HIGH, MEDIUM, or LOW for this issue. Please explain all LOW answers in the narrative block on the following page. Indications of HIGH performance should also be described in the narrative. Also note in the narrative block which of the focus issues are not applicable to this plant and any for which the evaluator cannot make a judgment.

	HIGH	*MEDIUM*	*LOW*
1. Management actions when problems arise. *[Consider: does management initiate actions when problems arise or only after inspection requires actions; will management independently reduce line speeds when problems occur, such as when fecal contamination is excessive or for high pathology flocks, etc.; does management add any additional and/or an adequate number of staff to the line when problems occur; do supervisors or QC/QA personnel work on the line when problems occur; who monitors employees, procedures, and practices when problems arise; etc.]*	☐	☐	☐
2. Management planning for emergencies. *[Consider: does management have a written emergency plan; does the plant have fire drills; does the plant train employees in safe escape routes, CPR, or emergency treatment of trauma victims, etc.; are signs posted for safe exit/escape routes in emergencies; etc.]*	☐	☐	☐
3. Management action during emergencies. *[Consider: how quickly does management react to an emergency situation; how is product protected during an emergency; are employees/supervisors trained and prepared to make decisions, assist, and lead employees in emergency situations; is there visible organization during emergencies, or chaos; etc.]*	☐	☐	☐

	HIGH	MEDIUM	LOW
4. Management plans and actions:			
• does management prepare plans in advance of problems, proactively and preventively.	☐	☐	☐
• are short-term improvements planned and programmed with a schedule that is followed.	☐	☐	☐
• are long-term improvements planned and programmed with a schedule that is followed.	☐	☐	☐
• does the plant have and follow any partial quality control programs.	☐	☐	☐
• does the plant consider sanitation in planning for improvements or expansion.	☐	☐	☐
• are most changes initiated by the plant to meet plant needs.	☐	☐	☐
• are most changes initiated by the plant to meet what inspection sees as product safety needs.	☐	☐	☐
• is management self-motivated to fix, replace, and repair facilities and equipment in the plant.	☐	☐	☐
• does management commit adequate financial and human resources to maintain plant facilities and produce safe product.	☐	☐	☐

Narrative

Please use the remaining space to record your impressions and comments about management's response to problems in this plant. Include an overall summary appraisal of the plant's operations related to this factor. Note any focus questions that did not apply in this plant. Describe instances of exemplary performance as well as shortcomings. Continue on additional sheets if necessary.

Factor IX — Plant Management Measures to Protect Product from Contamination Hazards

Purpose: Determine management attitudes, strategies, and actions taken to prevent contamination and cross-contamination hazards in production.

Focus Issues

Please observe and evaluate each issue described on the list provided below as indicators of overall plant performance for this factor. Check an appropriate block to indicate your judgment of whether **Plant Management Measures to Protect Product from Contamination Hazards** is HIGH, MEDIUM, or LOW for this issue. Please explain all LOW answers in the narrative block on the following page. Indications of HIGH performance should also be described in the narrative. Also note in the narrative block which of the focus issues are not applicable to this plant and any for which the evaluator cannot make a judgment.

	HIGH	*MEDIUM*	*LOW*
1. Management control and programs to prevent contamination from:			
• visitors in the plant.	☐	☐	☐
• product flow inside the plant.	☐	☐	☐
• product flow into and out of the plant.	☐	☐	☐
• employee traffic within the plant.	☐	☐	☐

[Consider: potential problems of product contamination due to the following: employees from maintenance, inedible, evisceration, processing, cooked product, or quality assurance departments; plant tours; visitors; equipment and supply vendors; etc.]

2. Management product protection programs and controls:			
• when poultry carcasses are contaminated with feces.	☐	☐	☐
• when carcasses or products fall on the floor.	☐	☐	☐
• layout of plant for proper product flow patterns.	☐	☐	☐
• layout of plant for proper ventilation and airflow.	☐	☐	☐

	HIGH	MEDIUM	LOW
• to manage employee traffic, e.g., to keep evisceration or offal employees out of processing areas.	☐	☐	☐
• to maintain adequate adjustment of automatic eviscerating equipment.	☐	☐	☐
• to maintain processing equipment properly.	☐	☐	☐
• to ensure the use of good manufacturing practices throughout the plant.	☐	☐	☐
• to ensure adequate separation of exposed raw from cooked products.	☐	☐	☐
• to prevent product contamination with foreign materials, i.e. metal, plastic, wood, paper, etc.	☐	☐	☐
• to ensure effective and sanitary salvage of products.	☐	☐	☐
• to prevent rust, flaking paint, or condensation contamination from overhead structures.	☐	☐	☐

[Consider: if there are written programs for these control points; if the programs are used and are effective; when contamination occurs, whether product is appropriately disposed of or salvaged; who supervises, monitors, and enforces these programs; if records of these programs and incidents of contamination are maintained and available to inspectors; if management uses these records and programs effectively; if the programs are approved by FSIS, such as PQC's; etc.]

Narrative

Please use the remaining space to record your impressions and comments about management measures to prevent contamination and cross-contamination in this plant. Include an overall summary appraisal of the plant's operations related to this factor. Note any focus questions that did not apply in this plant. Describe instances of exemplary performance as well as shortcomings. Continue on additional sheets if necessary.

Factor X — Product Quality and Safety

Purpose: Estimate the level of product quality according to health and safety attributes.

Focus Issues

Please observe and evaluate each issue described on the list provided below as indicators of overall plant performance for this factor. Check an appropriate block to indicate your judgment of whether **Product Quality and Safety** is HIGH, MEDIUM, or LOW for this issue. Please explain all LOW answers in the narrative block on the following page. Indications of HIGH performance should also be described in the narrative. Also note in the narrative block which of the focus issues are not applicable to this plant and any for which the evaluator cannot make a judgment.

	HIGH	*MEDIUM*	*LOW*
1. Management controls and programs:			
• are employees trained and encouraged to take independent actions to control and improve product quality and safety.	☐	☐	☐
• are processing procedures designed and written with multiple, inherent safety controls.	☐	☐	☐
• are plans prepared for prevention and control of production hazards.	☐	☐	☐
• do plans include an adequate safety margin built into processing procedures.	☐	☐	☐
• are product quality and safety intrinsically designed into the product by R&D.	☐	☐	☐
• does management take proactive preventive measures and prompt, appropriate reactions independently of inspection oversight.	☐	☐	☐
• does management keep inspection informed of problems and actions.	☐	☐	☐
• has management implemented effective Total Quality Control procedures and programs.	☐	☐	☐
• has management implemented effective Partial Quality Control procedures and programs.	☐	☐	☐

	HIGH	MEDIUM	LOW
2. Employees actions and attitudes:			
• are employees committed to product safety and quality.	☐	☐	☐
• do employees take independent actions when product safety and quality are involved.	☐	☐	☐
• are employees actively involved in production planning to provide information or suggestions to improve product quality and prevent problems.	☐	☐	☐

Narrative

Please use the remaining space to record your impressions and comments about management measures to enhance product quality in this plant. Include an overall summary appraisal of the plant's operations related to this factor. Note any focus questions that did not apply in this plant. Describe instances of exemplary performance as well as shortcomings. Continue on additional sheets if necessary.

Factor XI — Plant Management Programs and Systems

Purpose: Provide an overview of management process control, organizational structure to assure quality control, and programs and systems operating to produce safe, wholesome foods under adequately controlled good manufacturing practices.

Focus Issues

Please observe and evaluate each issue described on the list provided below as indicators of overall plant performance for this factor. Check an appropriate block to indicate your judgment of whether **Plant Management Programs and Systems** is HIGH, MEDIUM, or LOW for this issue. Please explain all LOW answers in the narrative block on the following page. Indications of HIGH performance should also be described in the narrative. Also note in the narrative block which of the focus issues are not applicable to this plant and any for which the evaluator cannot make a judgment.

	HIGH	*MEDIUM*	*LOW*
1. Management systems/programs that exceed minimal regulatory requirements. *[Consider: if the plant has and effectively uses any of the following programs: microbiological control monitoring program for sanitation; sanitizing hand or foot dips; Good Manufacturing Practices; memorandum of understanding for pre-slaughter certification for chemical residues; chemical analysis programs; etc.]*	☐	☐	☐
2. Management programs and systems:			
• does the plant follow its TQC procedures.	☐	☐	☐
• does the plant follow its PQC procedures.	☐	☐	☐
• does the plant update its programs as production changes are made.	☐	☐	☐
• does the plant perform in-house or other laboratory testing of products.	☐	☐	☐
• does the plant freely share laboratory results with inspectors.	☐	☐	☐
• are laboratory records readily available to inspectors.	☐	☐	☐
• does the plant allow/encourage inspectors to observe laboratory procedures.	☐	☐	☐

	HIGH	MEDIUM	LOW
3. Management QA/QC programs or systems. *[Consider: if the plant has and effectively uses any of the following programs: microbiological control monitoring program for sanitation; pH control; processing control for fat, water, etc.; SLD policy 110 for keep-refrigerated foods; etc.]*	☐	☐	☐
4. QC/QA department. *[Consider: if there is an adequate number of staff in QC/QA; if job responsibilities are appropriate to an individual's training, education, and background and adequate to job performance; if facilities, such as an adequate in-plant laboratory and laboratory equipment are provided; if there is a separate laboratory staff; the adequacy of the laboratory staff's training, education, and background for job responsibilities; the plant organizational relationship between production and QC/QA; the actual working relationship between production and QC/QA; the staff attitudes toward food quality and safety; etc.]*	☐	☐	☐
5. Laboratory facilities:			
• are an adequate in-plant laboratory facility and equipment available.	☐	☐	☐
• is it staffed by technically trained or educated	☐	☐	☐
• personnel such as microbiologists or chemists.	☐	☐	☐
• are adequate laboratory equipment and supplies provided and maintained for analyses in microbiology or food chemistry.	☐	☐	☐
• are product samples shipped to another outside laboratory for analyses.	☐	☐	☐
• is the laboratory accredited by FSIS.	☐	☐	☐
• are any laboratory analyses done except at FSIS laboratories at inspector's discretion.	☐	☐	☐

Narrative

Please use the remaining space to record your impressions and comments about how management programs and systems enhance product quality in this plant. Include an overall summary appraisal of the plant's operations related to this factor. Note any focus questions that did not apply in this plant. Describe instances of exemplary performance as well as shortcomings. Continue on additional sheets if necessary.

APPENDIX C

United States Department of Agriculture
Food Safety and Inspection Service

QUESTIONNAIRE

FOR INSPECTORS, INSPECTORS-IN-CHARGE (IIC's)

AND CIRCUIT SUPERVISORS (CS's)

INSTRUCTIONS

Please complete the following questions based on your knowledge of HACCP and its application in the volunteer plant. The questions ask you to assess 1) the level of HACCP implementation and 2) the adequacy of the HACCP principles as they have worked in the volunteer plant you inspect.

— Additional instructions for interviewers will be added —

QUESTIONNAIRE

FOR INSPECTORS, INSPECTORS-IN-CHARGE (IIC's)
AND CIRCUIT SUPERVISORS (CS's)

PROCESS CONTROL

1a) Are critical limits being used at each identified critical control point (CCP) in the plant?

Used at All CCP's	Used at Some CCP's	Not Used at Any CCP's	Don't Know
1	2	3	4

1b) Please identify at which CCP's critical limits are not in use (if applicable).

_____

_____

_____

_____

_____

2a) Does the HACCP system as implemented control the process?

Yes	No
1	2

2b) Please explain if "No."

_____

_____

_____

_____

3a) Do you see an improvement in process control under HACCP?

Yes	No
1	2

3b) Please explain.

_____

_____

_____

_____

_____

_____

RECORD KEEPING

4a) Is the plant using record-keeping procedures at each identified CCP?

Using at All CCP's	Using at Some CCP's	Not Using at Any CCP's	Don't Know
1	2	3	4

4b) Please identify at which CCP's record-keeping procedures are not in use.

_____

_____

_____

_____

_____

_____

5a) Are the plant's record-keeping procedures in accordance with the plant-specific HACCP plan at each CCP?

Yes for All CCP's	Yes for Some CCP's	Not for Any CCP's	Don't Know
1	2	3	4

5b) Please explain if record-keeping procedures are not in accordance with the plant-specific HACCP plan at each CCP.

_____

_____

_____

_____

_____

MONITORING PROCEDURES

6a) Are monitoring procedures being used at each identified CCP?

Yes for All CCP's	Yes for Some CCP's	Not for Any CCP's	Don't Know
1	2	3	4

6b) Please identify at which CCP's monitoring procedures are not in use.

_____

_____

_____

_____

_____

7a) Are monitoring procedures that are in accordance with the plant-specific HACCP plan being used at each CCP?

Yes for All CCP's	Yes for Some CCP's	Not for Any CCP's	Don't Know
1	2	3	4

7b) Please explain if monitoring procedures are not in accordance with the plant-specific HACCP plan at each identified CCP.

_____

_____

_____

_____

_____

_____

8a) Have the plant staff responsible for monitoring been identified?

Yes	No	Don't Know
1	2	3

8b) Please explain if you answered "No."

_____

_____

_____

_____

_____

_____

CORRECTIVE /PREVENTIVE ACTION

9a) Are corrective/preventive actions being used for each identified CCP?

Yes for All CCP's	Yes for Some CCP's	Not for Any CCP's	Don't Know
1	2	3	4

9b) Please identify at which CCP's corrective/preventive actions are not in use.

_____

_____

_____

_____

_____

10a) Are corrective/preventive actions that are in accordance with the plant-specific HACCP plan being used at each identified CCP?

Yes for All CCP's	Yes for Some CCP's	Not for Any CCP's	Don't Know
1	2	3	4

10b) Please identify at which CCP's corrective/preventive actions are not appropriate or are missing.

_____

_____

_____

_____

_____

INSPECTOR WORKLOAD

11a) What impact did HACCP have on your workload?

Increased Substantially	Increased Moderately	No Impact	Decreased Moderately	Decreased Substantially
1	2	3	4	5

11b) Please provide some specifics about the changes in your workload which have occurred (if any).

_____

_____

_____

_____

_____

_____

12) How did you coordinate your inspection activities under HACCP with your other inspection responsibilities? Please discuss.

_____

_____

_____

_____

_____

_____

WORKING RELATIONSHIPS

13a) How have your working relationships with FSIS personnel changed as a result of HACCP?

Working Relationships Improved	Working Relationships Stayed the Same	Working Relationships Got Worse
1	2	3

13b) Please explain any changes in FSIS working relationships.

_____

_____

_____

_____

_____

14a) How have your working relationships with plant personnel changed as a result of HACCP?

Working Relationships Improved	Working Relationships Stayed the Same	Working Relationships Got Worse
1	2	3

14b) Please explain any changes in your working relationships with plant personnel.

_____

_____

_____

_____

_____

14c) To what extent, if at all, did you feel that you and your coworkers experienced difficulty in overseeing the implementation of HACCP?

To Little Extent	To Some Extent	To a Moderate Extent	To a Great Extent	To a Very Great Extent	Don't Know
1	2	3	4	5	6

14d) What were the major hurdles that had to be overcome? [Ask respondent to rank order once listed.]

_____

_____

_____

_____

_____

14e) To what extent, if at all, did you feel that plant officials experienced difficulty in implementing HACCP?

To Little Extent	To Some Extent	To a Moderate Extent	To a Great Extent	To a Very Great Extent	Don't Know
1	2	3	4	5	6

14f) What were the major hurdles they had to overcome? [Ask respondent to rank order once listed.]

_____

_____

_____

_____

_____

PLANT MANAGEMENT

15) How receptive was plant management to adopting HACCP?

Very Receptive	Somewhat Receptive	Somewhat Unreceptive	Very Unreceptive	Don't Know
1	2	3	4	5

16a) How willing was plant management to take corrective/preventive action in response to HACCP violations in the presence of inspection personnel?

Very Willing	Somewhat Willing	Somewhat Unwilling	Very Unwilling	Don't Know
1	2	3	4	5

16b) How willing was plant management to take corrective/preventive action in response to HACCP violations in the absence of inspection personnel?

Very Willing	Somewhat Willing	Somewhat Unwilling	Very Unwilling	Don't Know
1	2	3	4	5

17) Please list the activities plant management took to prepare for the implementation of HACCP.

_____

_____

_____

_____

_____

18) **What events occurred during the HACCP test which may have affected the results of the test program?**

_____

_____

_____

_____

_____

_____

BACKGROUND INFORMATION

19) **What are your Standard Job Number (SJ#) and grade?**_____

20) **How long have you worked:**

a. In this plant?

- ☐ Less than one year
- ☐ One to three years
- ☐ More than three years

b. In meat and poultry inspection?

- ☐ Less than one year
- ☐ One to three years
- ☐ More than three years

21) **Have you had any previous experience in (...particular product involved in HACCP test...)? If yes, describe further.**

_____

_____

_____

_____

_____

_____

22) **What are the name and number of this establishment?**

_____

COMMENTS: **Do you have any additional insights concerning HACCP implementation issues or recommendations for improvement?**

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APPENDIX D

United States Department of Agriculture
Food Safety and Inspection Service

QUESTIONNAIRE

FOR PLANT PERSONNEL

INSTRUCTIONS

Please complete the following questions based on your knowledge of HACCP and its application in the volunteer plant. The questions ask you to assess 1.) the level of HACCP implementation and 2.) the adequacy of the HACCP principles as they have worked in the volunteer plant you inspect.

— Additional instructions for interviewers will be added —

QUESTIONNAIRE

FOR PLANT PERSONNEL

CRITICAL CONTROL POINTS (CCP's)

1a) Are critical limits being used at each identified critical control point (CCP) in the plant?

Used at All CCP's	Used at Some CCP's	Not Used at Any CCP's	Don't Know
1	2	3	4

1b) Please identify at which CCP's critical limits are not in use (if applicable).

_____

_____

_____

_____

2a) Is the number of CCP's correct?

No, One CCP Missing	No, Two CCP's Missing	No, Three or More Missing	Yes, All CCP's Identified	No, One or More Not Needed	Don't Know
1	2	3	4	5	6

2b) Please explain.

_____

_____

_____

_____

3a) **Are the critical limits used at each identified CCP in the plant in accordance with the plant-specific HACCP plan?**

Yes for All CCP's	Yes for Some CCP's	Not for Any CCP's	Don't Know
1	2	3	4

3b) **Please explain if you answered other than "Yes for All CCP's" and consider microbiological, chemical, and physical critical limits.**

4a) **Are the plant's record-keeping procedures burdensome at any CCP's?**

Yes for All CCP's	Yes for Some CCP's	Not for Any CCP's	Don't Know
1	2	3	4

4b) **Please explain.**

5a) Have the plant staff responsible for monitoring been identified?

Yes	No
1	2

5b) Please explain if you answered "No."

_____

_____

_____

_____

_____

6a) How have your working relationships with FSIS personnel changed as a result of HACCP?

Working Relationships Improved	Working Relationships Stayed the Same	Working Relationships Got Worse
1	2	3

6b) Please explain any changes in FSIS working relationships.

_____

_____

_____

_____

_____

6c) **To what extent, if at all, did you feel that you and your coworkers experienced difficulty in implementing HACCP?**

To Little Extent	To Some Extent	To a Moderate Extent	To a Great Extent	To a Very Great Extent	Don't Know
1	2	3	4	5	6

6d) **What were major hurdles that had to be overcome during the implementation phase? [Ask respondent to rank order once listed.]**

_____

_____

_____

_____

_____

6e) **To what extent, if at all, did you feel that FSIS officials experienced difficulty in overseeing the implementation of HACCP?**

To Little Extent	To Some Extent	To a Moderate Extent	To a Great Extent	To a Very Great Extent	Don't Know
1	2	3	4	5	6

6f) **What do you regard as the major hurdles they had to overcome during the implementation phase? [Ask respondent to rank order once listed.]**

_____

_____

_____

_____

_____

7) **How flexible were FSIS officials in responding to corrective/preventive actions for HACCP violations?**

Very Flexible	Somewhat Flexible	Somewhat Inflexible	Very Inflexible	Don't Know
1	2	3	4	5

PLANT MANAGEMENT

8) **What events occurred during the HACCP test which may have affected the results of the test program?**

_____

_____

_____

_____

_____

9) **What are the name and number of this establishment?**

_____

COMMENTS: **Do you have any additional insights concerning HACCP implementation issues or recommendations for improvement?**

_____

_____

_____

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_____

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_____

APPENDIX E

PEER RECOMMENDATIONS

The draft HACCP Evaluation Plan was reviewed by six peers with expertise in meat and poultry sciences, public health, statistical design, program analysis, and quality management programs. The peers are:

- Lt. Col. Dale Boyle, D.V.M., Office of the Surgeon General, U.S. Army;
- Eugene Gangarosa, M.D., Emory University School of Public Health;
- Charles Kendig, Xerox Corporation;
- James Marsden, Ph.D., American Meat Institute;
- Laszlo Papay, IBM Corporation; and
- David Theno, Ph.D., Theno & Associates.

The peers submitted written recommendations and met on March 7, 1991, with the FSIS Evaluation Team to discuss the Agency's draft. As a result of this meeting the peers offered the following recommendations.

1. The peers endorsed the five Evaluation Plan goals:

    - To evaluate the pre-implementation stages of HACCP models in the volunteer plants;
    - To evaluate the conformance of the model HACCP plans and the plant-specific HACCP models with the HACCP principles developed by the National Advisory Committee on Microbiological Criteria for Foods;
    - To evaluate the functioning and effectiveness of the plant-specific HACCP models in the volunteer plants;
    - To evaluate the functioning and effectiveness of a HACCP-based inspection system in the volunteer plants; and
    - To evaluate the potential impact for nationwide implementation of a HACCP-based inspection system in meat and poultry plants.

2. The peers endorsed the Agency's plan to hold in-plant correlation meetings among the FSIS headquarters personnel assigned to perform the plant reviews, before actually conducting the reviews.

3. The peers recommended that FSIS inspectors assigned to the test plants and assigned to collect the quantitative plant evaluation data remain the same throughout the baseline and data collection phases.

4. The peers recommended three phases of data collection. First, there will be a 3-month baseline data collection phase prior to implementing the plant-specific HACCP model. FSIS will collect the baseline data. Second, an implementation phase will be initiated to allow the test plants sufficient time to institute change and adapt to a new process. While the time necessary to complete this phase might vary from plant to plant, this phase will last at least 3 months. FSIS will conduct the data collection during phase II. Third, an operational phase will commence once phase II has been completed. FSIS will conduct this operational evaluation and data collection phase for 6 months.

5. The peers recommended the test plant and FSIS jointly agree when the test plant is ready to move from phase II to phase III. Until both parties concur, phase II will remain in effect.

6. The peers recommended that FSIS collect data throughout phases I, II, and III.

7. Given that phase II is designed to be a cooperative exercise with FSIS and industry working together to make the HACCP plan operational, the peers recommended that FSIS share phase II data with the test plants.

8. The peers recommended, when appropriate, that FSIS consider using plant data in addition to the data collected by FSIS during phases I, II, and III. The peers recognized that some plants may collect data similar to that outlined in the Evaluation Plan.

9. The peers agreed to review the sampling plans and protocol for the collection of microbiological, chemical, and physical data.

10. The peers agreed that testing for indicator organisms is essential to the evaluation of process control in the HACCP test plants. In addition, the peers recommended that Salmonella incidence and enumeration data should be collected in the poultry slaughter HACCP test plants.

11. The peers recommended deleting slaughter physical factor number 5 (poultry slaughter contamination).

12. The peers recommended that plants volunteering but not selected to participate in the HACCP Study be encouraged to proceed in adopting HACCP in their operations. The peers recommended that FSIS provide the generic HACCP models and relevant literature to these plants.

13. The peers recommended that the survey instruments should be designed to measure attitudinal and cultural changes that may be experienced when HACCP is implemented.

14. The peers recommended reviewing the qualitative plant data instrument to allow for more specificity and factual determinations. The peers recommended that FSIS use this data as supportive evidence and as an adjunct to the quantitative data.

15. The peers recommended using the qualitative plant data instrument nationwide, beyond the HACCP Study. The peers agreed this national effort was not necessary for the HACCP Study and could be considered at a later date.

16. The peers agreed with the Agency's inclusion, in the survey of plant personnel, of a request for feedback from the HACCP test plants concerning HACCP implementation and recommendations for improvement.

17. The peers recommended the evaluators of the qualitative plant data be properly trained in conducting the surveys and assessing the results.

18. The peers agreed it is valid to survey in-plant inspectors and plant personnel involved with implementing HACCP, although the peers suggested modifying some of the questions to solicit more feedback. The peers recommended that the survey data should be viewed as an adjunct to the quantitative data.

19. The peers recommended field testing the in-plant survey prior to its administration.

20. The peers recommended the Agency convert the HACCP model questionnaire to a mandatory checklist. The checklist would be used to verify that the generic models and plant-specific plans conform with the principles recommended by the National Advisory Committee on the Microbiological Criteria for Foods. The HACCP plan must score 100 percent on the checklist, unless there are checklist items that are not applicable. HACCP plans should not be implemented in a plant that registers any negative checklist categorizations.

Following the peers' acceptance of the 20 recommendations, four additional recommendations were suggested and agreed upon by the peers.

21. The peers recommended the Agency share phase I (baseline) data with the test plants.

22. The peers recommended that quantitative microbiological test protocols for pathogenic organisms be uniform for ground beef, poultry slaughter, and swine slaughter.

23. The peers recommended that all data collected by FSIS during the HACCP Study should be confidential. Furthermore, the peers recommended if confidentiality cannot be maintained for pathogenic organism data, then microbiological testing should be limited to indicator organisms.

24. The peers recommended that chemistry data collection should include salt analysis not brine content, unless brine content is considered a critical control point.

The Agency accepts the 24 peer recommendations. The final HACCP Evaluation Plan has incorporated these recommendations.